Modification and preliminary evaluation of an intervention to improve wellbeing in psychosis

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Modification and preliminary evaluation of an intervention to improve wellbeing in psychosis

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May 2014
Abstract

Positive Psychotherapy (PPT) is a psychological intervention developed in the discipline of Positive Psychology, which aims to improve wellbeing by fostering strengths, resources, and positive experiences. This thesis describes the adaptation and preliminary evaluation of PPT for people with psychosis.

A systematic review identified the evidence base relating to wellbeing in people with psychosis and developed a conceptual framework of wellbeing. A subsequent qualitative study with 23 service users with psychosis and 14 mental health service staff validated the framework and identified suggestions for adapting PPT. Suggested changes were presented to an expert panel. An intervention model and manual for adapted PPT – called WELLFOCUS PPT – were developed.

The model and intervention were tested in a pilot randomised controlled trial (ISRCTN04199273). 94 patients with psychosis were individually randomised in blocks to receive either 11 weekly group sessions of WELLFOCUS PPT in addition to treatment as usual (TAU), or TAU only. Assessments occurred pre-randomisation and post-therapy. The primary outcome was wellbeing (Warwick-Edinburgh Mental Wellbeing Scale). Secondary outcomes included symptomatology, depression, self-esteem, empowerment, hope, sense of coherence, savouring beliefs, and functioning, all according to standardised definitions. ANCOVA was used to estimate the main effect of group on all outcomes. Nested process evaluation involving interviews and focus groups with intervention group participants (n=37) and therapists (n=7) assessed the feasibility and trial processes.

Intention-to-treat analysis showed no main effect of WELLFOCUS PPT on wellbeing, but significant effects on symptoms (p=.006, ES=0.42). Additional analysis adjusting for therapy group increased the effect on symptoms (p=.004, ES=0.43). After adjusting for age and gender, improvement in depression also became significant (p=.005). The intervention was well received, with suggested adaptations for optimising understanding, maintenance, and therapist involvement. A future definitive RCT might focus on symptomatology, for which a complete sample size of about 168 would be required to show significant results.
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## Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>ANCOVA</td>
<td>Analysis of Co-Variance</td>
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<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
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<tr>
<td>BPRS</td>
<td>Brief psychiatric Rating Scale</td>
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<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
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<tr>
<td>CI</td>
<td>Confidence Interval</td>
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<tr>
<td>CORE10</td>
<td>Short measure of psychological distress for routine use in psychological therapies</td>
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<td>ES</td>
<td>Effect Size</td>
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<tr>
<td>GAF</td>
<td>Global Assessment of Functioning</td>
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<td>HoNOS</td>
<td>Health of the Nation Outcome Scale</td>
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<td>IHS</td>
<td>Integrative Hope Scale</td>
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<tr>
<td>ITT</td>
<td>Intention to Treat</td>
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<tr>
<td>MANSA</td>
<td>Manchester Short Assessment of Quality of Life</td>
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<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>ONS</td>
<td>Office of National Statistics</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>PP</td>
<td>Positive Psychology</td>
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<tr>
<td>PPI</td>
<td>Positive Psychotherapy Inventory</td>
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<td>PPT</td>
<td>Positive Psychotherapy</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>RES</td>
<td>Rogers Empowerment Scale</td>
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<tr>
<td>R-SES</td>
<td>Rosenberg Self-Esteem Scale</td>
</tr>
<tr>
<td>SBI</td>
<td>Savouring Beliefs Inventory</td>
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<tr>
<td>SCS</td>
<td>Sense of Coherence Scale</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<td>SDHS</td>
<td>Short depression Happiness Scale</td>
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<tr>
<td>TSC</td>
<td>Trial Steering Committee</td>
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<td>WEMWBS</td>
<td>Warwick-Edinburgh Mental Wellbeing Scale</td>
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On a private level, I want to thank my partner Stefan for embarking on this adventure together with me. And of course I want to thank our families, especially my parents, who took it upon them to travel to the UK many times to babysit and support me in busy times.
For Clara.
We did this together.
Chapter 1: Introduction

This chapter provides a brief overview of what will be covered in this thesis. Section 1.1 introduces the concepts of wellbeing and positive psychotherapy. Section 1.2 describes the aims and locates the work within a scientific framework. Section 1.3 outlines the structure for the thesis, Section 1.4 lists the publications resulting from this thesis, and Section 1.5 describes the student’s contribution to the overall work.

1.1 Introduction to the thesis

This thesis is about wellbeing in the context of severe mental illness, specifically about improving wellbeing for people with psychosis. Wellbeing, as briefly defined later in this Chapter and outlined in detail in Chapter 2, is an important outcome of personal recovery from severe mental illness (Slade 2010) and it is the focus of the academic discipline of Positive Psychology (Seligman and Csikszentmihalyi 2000). The concepts of recovery and Positive Psychology are relatively recent developments, reflecting a change in understanding of mental health and mental illness. These background areas, i.e. mental illness, mental health and recovery; wellbeing; and Positive Psychology are briefly introduced now.

Mental illness, mental health and recovery

The disciplines of both psychiatry and psychology have traditionally attended to mental illness and deficit. As a medical discipline psychiatry comes with a classification of disorders, and psychiatric research advances the knowledge of how to treat these disorders and alleviate suffering. However, since the mid-19th century there is reference to public health endeavours and to ‘mental hygiene’, which focused on activities and techniques to promote and maintain mental health. The term ‘mental health’ later replaced ‘mental hygiene’ and was taken up by the World Health Organisation in its constitutions, to describe a state of ‘wellbeing’ (Bertolote 2008). Today, the general use of the term ‘mental health’ is still imprecise. It is often used as a synonym of psychiatry, as a complementary field thereof, or even as a euphemism for mental illness.

In the field of psychology, there have been repeated attempts to refocus the discipline towards more positive or strengths and resource based approaches, as described in Chapter 3. In the field of psychiatry, the most recent shift in the understanding of psychiatric conditions and psychiatric practice has evolved from the ‘mental health’
consumer/user/survivor movement, which introduced a new, additional, focus on personal experience and on individual development as a consequence of mental illness instead of just symptoms. In parallel, psychiatric research saw an increased professional interest in remission, functioning, and improvement of mental health. Consequently, two concepts of ‘recovery’ arose, i.e. that of clinical recovery, focusing on symptom remission and functioning (Harvey and Bellack 2009), and that of personal recovery which is framed as a journey of personal development and as a subjective process rather than being an outcome (Jaeger and Hoff 2012). Clinical recovery is defined by criteria such as improvement in certain symptom and functioning scores over defined periods of time (Jääskeläinen et al. 2013), while personal/social recovery comprises psychological domains such as identity, social connectedness, hope, empowerment, meaning in life, and wellbeing (Leamy et al. 2011). Concepts of clinical and personal/social recovery are both in use in modern mental health services today, with service provision focusing on improving symptoms and functioning as well as wellbeing. Specific intervention programmes have been developed to help address both understandings of recovery, for example introducing a stronger focus on personal wellness whilst coping with illness (Cook et al. 2012) or helping staff better understand and adopt the concept of personal recovery (Slade et al. 2011). However, few interventions specifically address wellbeing in people with severe mental illness (Schrank et al. 2013a).

Wellbeing

While the introduction of wellbeing as an outcome of mental health services is a relatively recent development, the concept of wellbeing itself has a long history. In the research literature the term arguably first emerged at the turn of the 19th/20th century in the context of economic research. A wealth of research followed in the 20th century introducing an abundance of conceptual understandings of wellbeing. There is still no universally accepted definition of the concept of wellbeing in the literature today. However, in relation to mental health, two relevant strands of understanding can be identified. One is the medical understanding of health-related quality of life, and one is the psychological understanding of subjective wellbeing and positive mental health. This psychological understanding of wellbeing has received increased attention in research on mental health promotion and recovery (Tennant et al. 2007a, Office of National Statistics 2012). A detailed description of the existing frameworks for wellbeing and their relevance to mental health research and practice is provided in Chapter 2.
Improving wellbeing is the focus of the discipline of ‘Positive Psychology’ (PP), which addresses positive aspects of human experience, strengths and positive resources (Seligman and Steen 2005). PP was introduced by US American Psychologist Martin Seligman and his colleague Mihaly Csikszentmihalyi in 1998 as a (self-proclaimed) movement to shift the focus of psychology away from a perceived prevailing deficit orientation through studying positive emotion, positive character strengths, and positive institutions (Seligman and Csikszentmihalyi 2000). PP is not the first initiative in psychology to focus on positives. Previous positive or resource oriented approaches included, for example, the mental hygiene movement, Gestalt therapy, existential analysis, or humanistic psychology. A detailed description of Positive Psychology, its definitions, predecessors, and criticisms is provided in Chapter 3.

One criticism of PP relevant to this thesis is the lack of a definition for the word ‘positive’ and the fact that the boundaries of the field of PP remain blurred in the literature. Hence, this thesis distinguishes between ‘Positive Psychology’ as a trademark and ‘positive psychology’ as a generic term. Positive Psychology as a trademark refers to psychological research and practice that relates explicitly or implicitly to the ideas introduced by Seligman or Csikszentmihalyi. Positive Psychology in this context will be abbreviated as PP. The more generic term of positive psychology (or positively focussed psychology) refers to all psychological research and practice that focuses on value, resource and strength oriented approaches to attaining wellbeing, happiness, or a good life, regardless of the theoretical background it evolved from. Furthermore, the term ‘positive’, in principle, will be treated as a purely individually defined label, without applying any philosophical or ethical background considerations.

1.2 Aims of the thesis

The goal of this thesis is to develop and test an intervention to improve wellbeing in people with psychosis, as defined by the diagnostic categories F20 and F31 according to ICD-10. Given the ambiguities surrounding the conceptualisation of wellbeing as an outcome, this involves an initial stage of understanding wellbeing in this client group. The thesis has three aims.

Aim 1 is to develop a theory-based and testable model of wellbeing for people with psychosis. This aim has two objectives. Objective 1.1 is to characterise the evidence base relating to wellbeing in people with psychosis, including the identification of
existing interventions to improve wellbeing. Objective 1.2 is to develop and validate an organising conceptual framework of wellbeing, including processes of change involved in wellbeing.

Aim 2 is to develop and manualise an intervention to increase wellbeing for people with psychosis. This aim has three objectives. Objective 2.1 is to develop an intervention to increase wellbeing in people with psychosis. Objective 2.2 is to manualise the new intervention in a way suitable for use in the current project and replication elsewhere. Objective 2.3 is to develop a testable model of the effectiveness of the new intervention.

Aim 3 is to undertake a pilot randomised controlled trial (RCT) to evaluate the new intervention in people with psychosis. This aim has two objectives. Objective 3.1 is to develop the methodology for a pilot RCT. Objective 3.2 is to test the developed intervention model and manual in a pilot RCT involving service user participants with psychosis.

*Scientific framework for the thesis*

The scientific framework for this thesis is the Medical Research Council (MRC) framework for the development and testing of complex interventions (Craig et al. 2008). This framework has four stages.

Stage 1 (‘Development’) first deals with identifying existing evidence in order to develop the intervention to a point where it can be expected to have a beneficial effect. Conducting a systematic literature review is recommended where no recent and relevant review exists. This is followed by the identification and development of theory, outlining the rationale for the intervention and the likely processes of change. The development of theory may build on existing evidence, and be supplemented with new research. The theory forms the basis for the development of a testable model specifying the intervention, the involved processes, and the expected outcomes.

Stage 2 (‘Feasibility and piloting’) involves assessing the feasibility of the developed complex intervention and the methods of evaluating it. This includes assessing acceptability, compliance, delivery, recruitment, retention, and effect size for the power calculation for a subsequent definitive RCT. Such a pilot trial aims to examine key uncertainties that may need to be resolved in order for a definitive RCT to be successful.
Stage 3 (‘Evaluation’) involves the evaluation of the intervention using appropriate design choices for the given circumstances. An experimental approach considering randomisation is recommended as the most robust method of preventing selection bias. Primary and secondary outcome measures and measurement of potential confounders should be carefully chosen, as informed by the pilot study. Nested process evaluation is recommended to establish fidelity and quality of the implementation of the intervention, explore its consequences, and ways to further optimise it, to clarify causal mechanisms, and identify contextual factors associated with variation in outcomes.

Stage 4 (‘Implementation’) involves the routine implementation of the new intervention, surveillance and monitoring, and long-term follow-up.

The stages of the framework are conceptualised as cyclical rather than linear, with results from any stage potentially informing not just the next stage but also feeding back into earlier stages in the continuous improvement and increasingly higher level evaluation of the intervention (Craig et al. 2008).

This thesis involves a comprehensive process evaluation in the context of a Stage 2 pilot trial of a theory-based intervention. The thesis therefore spans Stages 1 and 2 of the MRC Framework. Figure 1.1 shows the aims, study design and outcomes of this thesis mapped onto the MRC framework.


1.3 Structure of the thesis

Chapters 2 and 3 are introductory chapters providing an overview of the literature, each based on a comprehensive but not systematic review. Chapters 4 to 8 describe the work undertaken to meet the objectives of the research programme, and Chapter 9 is a discussion of the overall thesis.

Specific content of the chapters

Chapter 2 outlines the evolution of concepts of wellbeing over time with a particular focus on wellbeing in the context of mental health.

Chapter 3 provides an introduction to Positive Psychology and Positive Psychotherapy.
Chapter 4 describes the systematic literature review undertaken to characterise the evidence base relating to wellbeing in people with psychosis, including the identification of existing interventions to improve wellbeing (Objective 1.1) and the development of an initial organising framework, i.e. the ‘static framework of wellbeing’ (Objective 1.2).

Chapter 5 covers the qualitative sub-study with service users with psychosis and mental health service staff which served to validate the static framework and develop the ‘dynamic framework of wellbeing’ including processes of change (Objective 1.2). Data from the same qualitative sub-study also contributed to developing the new intervention (Objective 2.1), manual (Objective 2.2) and the testable model of the effectiveness of the new intervention (Objective 2.3), as described in Chapter 6.

Chapter 6 describes the development of the intervention manual and model.

Chapter 7 describes the methods developed for conducting the pilot RCT (Objective 3.1).

Chapter 8 describes the results of the pilot RCT (Objective 3.2).

Chapter 9 discusses the overall project and its results and provides conclusions and implications of the thesis.
1.4 Publications resulting from the thesis

Three papers from this thesis have been accepted for publication in peer-reviewed journals. Two of the three papers are included in the body of thesis chapters together with additional information to further elaborate on the work undertaken.


One further paper published in a peer reviewed journal that corresponds with the content of Chapter 2 is shown in Appendix 1.


1.5 Student’s contribution to the work

The thesis was undertaken in the context of a larger research project. I was involved in developing the funding application as a co-applicant. During the project I conducted, under supervision, the entire work for Aim 1 and Aim 2, including all interviews for the qualitative study part and leading all qualitative analyses. Additional input into papers was received from other research workers, listed as co-authors on the published work, e.g. for double-coding or reliability checks. Organisation of the expert consultation meeting for manual development and writing up the manual (and corresponding publication) was supported by an additional researcher.

I developed the methodology for the pilot RCT, and six additional research workers contributed to conducting the outcome assessments and process evaluation interviews, quantitative data entry and analysis, and qualitative data transcription. Contributions by other staff occurred under my direct day-to-day supervision as project manager, and Mike Slade’s overall supervision as primary investigator.
Chapter 2: Wellbeing: from objectivity to subjectivity

Wellbeing has been a topical policy focus in recent years and has attracted research interest across health conditions. However, an explicit description of the concept of wellbeing is often absent in research (Schrank et al. 2013a). This chapter provides an overview on the various concepts of wellbeing in the literature and their related measurement tools, with a specific reference to mental health. In examining the definitions of wellbeing, four academic strands of wellbeing research are identified:

*Economic strand:* grounded in economic research, wellbeing is framed in terms of national wealth, social determinants, development and general quality of life.

*Medical strand:* grounded in medical research, wellbeing is framed in relation to disorder and illness.

*Psychological strand:* Grounded in psychological research, wellbeing is framed in terms of subjective and mental concepts.

*Integrative strand:* informed by economic, medical, and psychological strand, with a distinct focus on positive psychology and recovery research.

The chapter discusses each strand, with particular focus on the psychological strand and its evolution into the contemporary, integrative strand. The primary focus is to show how wellbeing has shifted from being conceived as a collectivist concept with objective measures, to being conceived as an individualistic concept with subjective measures. This transition was instrumental in wellbeing becoming a key concept in mental health.

### 2.1 The economic strand of wellbeing research

Measuring and comparing the wellbeing of populations (rather than individuals) was first undertaken by economists in the early 20th century. Initially, financial indicators of wellbeing such as Gross National Product (GNP) were used to measure and compare. However, as these failed to discriminate between countries of similar developmental status, alternative economic indices were proposed to estimate societal functioning, including health, nutrition, income distribution and education (Cummins et al. 2003). Such indices are assumed to depend only partly on the total wealth of a nation because of unequal economic growth and distribution inequalities and hence better capture actual developmental states (Hicks and Streeten 1979).
The introduction of social indicators into economic and developmental research is an example of *proxy measures*, which are also widely used in all other research traditions outlined in this chapter. Proxy measures are typically used when a concept or condition cannot be exactly measured, e.g. because direct measurement would be too complex or costly. They instead assess something considered similar enough to reflect the targeted condition simplifying the assessment of target outcomes. Limitations of proxy measures mainly pertain to meaningfulness and statistical properties. These include: the difficulties of precisely defining both the target outcome and the proxy measure; finding a measure that correlates closely enough with the target outcome; and measurement error in data gathered at the population level (Fowler et al. 1998). All of these limitations pose potential problems to the measurement of population wellbeing using proxy measures.

Indeed, correlations between social indicators and the GNP differ greatly across studies, and overall are modest (Hicks and Streeten, 1979). The introduction of *composite measures* further increased the validity of wellbeing estimates. Composite measures combine different items within scales and indexes and determine a score that represents the target concept. Composite measures for population wellbeing initially included purely objective measures based on secondary data, such as literacy, clean water supply, or primary school enrolment. Later ‘subjective’ indicators, such as affect, wellbeing, or life satisfaction were added to capture how people actually feel about their lives (Glock 1976). Composite measures of population wellbeing are still developed today. The UK Office for National Statistics (ONS) has recently developed a new assessment of population wellbeing, including subjective domains such as spirituality, personal and cultural activities, political participation, or life satisfaction in addition to environmental and sustainability issues and UK economic performance (Office of National Statistics 2012).

Economic concepts of wellbeing overlap with medical and psychological concepts. Specifically, inclusion of objective social indices, e.g. mortality, into composite measures evolving from economic research signifies the emergence of the medical strand of wellbeing research. The addition of subjective measures, e.g. life satisfaction, signifies the emergence of the psychological strand of wellbeing research.
2.2 The medical strand of wellbeing research

In the economic phase, wellbeing is conceived of primarily in collectivist terms. Medical research marks the beginning of a shift in that it emphasises individual health status in understanding wellbeing and is strongly connected to the concept of quality of life. This concept also originated from the economic approach to wellbeing. From an economic or developmental perspective, quality of life (QoL) typically covers factors such as security, peace, equality of opportunity, participation, and personal satisfaction (Hicks and Streeten 1979). Health research is another major application of the concept of quality of life, in this context called health related quality of life (HRQoL).

HRQoL has attracted substantial research interest since its introduction, as well as criticism for lack of uniformity and clarity. The terms ‘health related quality of life’, ‘quality of life’ and ‘wellbeing’ are often used interchangeably, and only a few articles claiming to measure HRQoL provide a definition or identify constituent domains (Connell et al. 2012 1994). Conceptualisations and measures of HRQoL can be described according to a number of defining features, e.g. generic versus disease specific, or objective versus subjective. Individual measurement tools often cover widely different dimensions, including access to resources and opportunities, environmental factors, social relationships, employment, leisure activities, sex life, mobility, or satisfaction with social domains. The unifying feature of HRQoL concepts is their focus on illness symptoms and functioning based on the assumption that illness and disability inhibits full wellbeing (Kaplan 1976).

While physical health symptoms and functioning are major domains within HRQoL, measurement tools also often use the terms wellbeing and mental health (i.e. the absence of mental illness symptoms) interchangeably (Bech et al. 2003). Examples of generic HRQoL measures with a mental health or wellbeing sub-scale include the World Health Organization Quality of Life (WHOQOL) questionnaires with their domain on ‘psychological health’ (Skevington and McCrane 2012), the European Quality of Life-5 Dimensions questionnaire (EQ-5D) with its ‘anxiety and depression’ domain (EuroQol Group 1990), or the Short Form (SF) measures, with their ‘emotional wellbeing’ domain assessing feeling happy, sad, depressed, or anxious (Hays and Morales 2001). Other scales use a more elaborate conceptual foundation grounded in and overlapping with psychological conceptions of wellbeing. For example, the mental health specific Lancashire Quality of Life Profile (van Nieuwenhuizen et al. 2001) and
the Manchester Short Assessment of Quality of Life (Priebe et al. 1999) base their wellbeing domain on concepts of affect balance, life satisfaction and happiness.

At least three specific issues arise when assessing HRQoL in people with mental disorders. First, physical functional impairments such as reduced mobility or pain are often contained especially in generic HRQoL measures supposed to be applicable across health conditions. These domains may not be relevant for people with mental disorders. A second caveat is the potential distortion of subjective assessments due to ‘psychopathological fallacies’, most prominently the ‘affective fallacy’ which indicates that the momentary affective state can influence people’s judgement about their overall life (Katschnig 2005). This is most problematic in cases where HRQoL measures contain ‘emotional’ items relating to feelings of depression and anxiety, for example in the Quality of Life in Depression Scale (Hunt and McKenna 1992). The inclusion of emotional items may at the same time introduce measurement redundancy into studies, leading to false positive results when correlating HRQoL with other measures capturing mental health problems (Katschnig 2005, Bullinger 1997). Quantitative results support the ‘affective fallacy’, as depressive symptoms have been shown to have an independent and significantly negative effect on subjective ratings of HRQoL (Mechanic et al. 1994). The third concern relates to the reliability of subjective assessment in people with psychiatric disorders.

These concerns led to the inclusion of supposedly objective assessment methods, derived from clinicians or family members (Katschnig 2005). However, subjective assessment has become more accepted as people with severe mental illness were shown to reliably and consistently complete self-rating questionnaires (Vothknecht et al. 2011). Moreover, the views of clinicians and family members may be biased, and service users’ subjective position is argued to be no less valid simply because it diverges from an outsider perspective. In fact, ‘insider’ and ‘outsider’ perspectives have been shown to differ due to differing values placed on contextual factors and a tendency towards a negative bias from the outsider perspective (Wright and Lopez 2005). This supports the meaningfulness of the subjective assessment of wellbeing. Whilst both subjective and objective measures of HRQoL still coexist, the psychological approach has completely shifted to subjective assessment (McDowell 2010, Böckerman et al. 2011, Bettazzoni et al. 2008).
2.3 The psychological strand of wellbeing research

Psychological research has created specific concepts and measures to capture wellbeing in its own right. As with HRQoL, a review on psychological concepts of wellbeing criticised frequently missing or ambiguous definitions and the interchangeable use of similar terms (Kiefer, 2008). Distinctive features of the psychological approach include a focus on subjective experience and personal feelings, and on positive mental health and functioning, e.g. positive affect, life satisfaction, autonomy, competence or personal growth (McDowell 2010, Böckerman et al. 2011, Bettazzoni et al. 2008). Moreover, specific wellbeing concepts allow for peak experiences (e.g. peak positive affect) (Magyar-Moe 2009). Such specific states of wellbeing may bring symptomatic relief without being captured by measures of HRQoL.

The differences between measures of HRQoL and psychological wellbeing are empirically supported by their only moderate statistical correlations. Factor analysis including twelve scales assessing HRQoL and seven psychological wellbeing scales showed the two concepts to generally load on separate factors. Correlations between these scales ranged between 0.05 and 0.63, but were mostly around 0.2 to 0.4 (Spiro and Bosse 2000).

Despite broad agreement that wellbeing is a subjective condition in which positive feelings dominate, the detailed elements of wellbeing in the psychological approach remain a matter of discussion. Diverging views are often grouped under two broad perspectives: hedonic and eudemonic. The roots of these terms can be traced back to Greek mythology and complex understandings have been attached to them in philosophy over the centuries. In a psychological context today, hedonism usually refers to maximising pleasure and happiness while reducing pain. Pleasures may derive from any source, be it the body, the mind or the attainment of a valued outcome (Ryan and Deci 2001). The eudemonic perspective maintains that not all desires yield wellbeing when achieved, even though they might produce pleasure. Instead, wellbeing means to live in accordance with one’s true self and derives from personal growth and self-actualisation, from actively contributing, holding virtue and doing what is right. Happiness may be a pleasant result of this way of living but not its core (McDowell 2010, Ryan and Deci 2001).

Another organising principle for psychological wellbeing concepts is the distinction between the absence of mental illness symptoms and the presence of positive mental
health, e.g. framed as positive emotion. This is reflected in an increasing focus on positively framed items in wellbeing questionnaires.

One rationale for including positively framed variables (e.g. “I have felt cheerful and in good spirits”, “I woke up feeling fresh and rested”) in measurement tools was the observation that psychological distress is only rarely reported in general population samples (Veit and Ware 1983). This introduces a ceiling effect (Bech et al. 2003), i.e. a zero score on a depression scale indicates the absence of depression but not the presence of happiness (Joseph and McCollam 1993). Including characteristics of psychological wellbeing (e.g. zest, interest in and enjoyment of life) increases measurement precision and distinguishes among persons receiving perfect scores on measures of psychological distress (Veit and Ware 1983). For example, the Depression-Happiness-Scale (Lewis et al. 2000) refers to both happiness and depression conceptualised as opposite ends of a single continuum (Joseph and McCollam 1993). The WHO-5 goes one step further. It contains only positive items to assess emotional wellbeing. However, although framed positively, the WHO-5 still covers core dimensions of depression and proved to be a sensitive tool for screening for depression and suicide risk (Sisask et al. 2008, Schneider et al. 2010). This may indicate that simply rewording negative to positive items may not be sufficient to meaningfully capture wellbeing.

The complex interrelations between the mental health domain in HRQoL and assessment tools designated to specifically measure mental health or wellbeing are further exemplified by the RAND health survey. The original survey included the 38-item Mental Health Inventory (MHI-38) to assess mental health (Veit and Ware 1983). The MHI-38 had assimilated 15 questions from Dupuy’s General Wellbeing Index (McDowell 2010, Dupuy 1984). Later, the MHI-38 was condensed into the 5-item MHI-5, which was in turn used as the mental health sub-scale in the ‘Short Form’ HRQoL measures (e.g. SF-36 and SF-20) (Ware and Sherbourne 1992, Bullinger 1997). In addition, from the same item pool some items were adapted into the WHO-5, which aims to assess positive mental wellbeing, i.e. in this case defined as the opposite of depressive symptoms (McDowell 2010, Bech et al. 2003). These measurement overlaps show the gradual development from purely deficit-focused standard HRQoL measures to measures of positive wellbeing, mirroring the gradual overlap between the medical strand and the psychological strand of wellbeing.
Measuring subjectivity in the psychological phase

Despite their contrasts, the hedonic and eudemonic views are not independent but overlap conceptually and correlate with each other with varying magnitude (McDowell 2010, Ryan and Deci 2001). The same issue of contrasting but overlapping dimensions also applies to a view of wellbeing as lack of mental illness versus positive mental wellbeing, or negative versus positive affect (McDowell and Praught 1982). Hence, measurement tools for wellbeing may be better described according to their focus on affective, cognitive and multidimensional components.

Affective measures

Assessment tools that conceptualise wellbeing in terms of affect assume that wellbeing is the degree to which positive feelings outweigh negative feelings. They measure positive and negative emotions either as two distinct dimensions resulting in separate scores or in one overall ‘balance score’. Examples include the Positive and Negative Affect Scale (PANAS) (Watson et al. 1988), Bradburn’s Affect Balance Scale (ABS) (McDowell and Praught 1982), the Affectometer (Tennant et al. 2007b) or the Everyday Feeling Questionnaire (Uher and Goodman 2010). The evident overlap between affective wellbeing measures and measures of psychiatric symptoms is empirically supported by high correlations, especially with depression (Lewis et al. 2000).

Similar to the unresolved challenges in the relationship between mental illness and wellbeing, the relationship between positive and negative affect is complex. Positive and negative affect may be regarded as polar opposites but also as independent but correlated entities lying on a continuum (Russell and Carroll 1999). Varying correlation between variables measuring positive and negative affect have been attributed to imprecise wording of assessment tools, to the time frame (i.e. momentary versus long term questions) and to response format (Russell and Carroll 1999), as well as to a confusion of frequency and intensity of affective states, or simply to measurement error (Ryff 1989). One proposed solution for the controversy is the circumplex model of affect (Watson et al. 1999), one adaptation of which incorporates the idea of hedonic and eudemonic wellbeing (McDowell 2010), as shown in Figure 2.1.
Figure 2.1: Example of a circumplex model of wellbeing

The circumplex model of affect contains different mood states and qualities and allows for differing correlations between them. This model might serve as a useful template for explaining the relationship between mental illness and wellbeing, as discussed in Section 2.4.

**Cognitive measures**

Affective and cognitive measurement strategies overlap. An example for the intersection between emotional and cognitive understandings of wellbeing is Diener’s concept of ‘subjective wellbeing’ and the corresponding Satisfaction With Life Scale (Diener et al. 1985) which assesses positive affect and subjective life satisfaction. Similarly, the Oxford Happiness Inventory defines happiness as a combination of positive affect or joy, satisfaction, and the absence of distress and negative feeling (Hills and Argyle 2002).

Purely cognitive measures of wellbeing include single item questionnaires asking one question such as “How satisfied are you with your life overall?” or “Taking everything into consideration, how would you say you are today?” (McDowell 2010). This requires respondents to reflect on their overall state of life including all individually
relevant domains (Cummins 1998). As with HRQoL, the ‘affective fallacy’ caveat applies to global cognitive ratings, as they may be influenced by momentary affective states (Schwarz and Clore 1983). At the same time global ratings are thought to better reflect subjective valuation since different areas of life may be valued differently by individuals (Diener et al. 1999, Ryff and Keyes 1995).

Global cognitive measures of wellbeing have been widely applied and inspired the theory of ‘subjective wellbeing homeostasis’. This theory is based on the finding that mean population values of overall life satisfaction typically vary only within a narrow range. On a scale from 0 to 100, people in Western countries answer the question for overall life satisfaction roughly around 75, in non-Western countries the average lies around 70 (Cummins 2003, Cummins 1995). The theory of subjective wellbeing homeostasis is comparable to the homeostatic regulation of body functions. It proposes that subjective wellbeing is maintained within narrow margins (a ‘set point’) by a set of psychological devices, e.g. cognitive bias, personality factors, and adaptation (Cummins and Nistico 2002, Brickman et al. 1978, Cloninger and Zohar 2011). Hence, people maintaining a normally functioning homeostatic system show little fluctuations in wellbeing as a consequence of normal variations in their living conditions. Only highly unusual events cause the level of global subjective wellbeing to change temporarily, but it will return to its previous level over time, e.g. the subjective happiness of both lottery winners and paralyzed accident victims soon returns to previous levels (Brickman et al. 1978). The conclusions that may be drawn for the measurement of wellbeing in general are that the classic ‘life as a whole’ question is useful as an estimate of the personal set-point of wellbeing, but may be unlikely to change as a result of a therapeutic intervention (Oswald and Wu 2010).

**Multidimensional measures**

Multidimensional wellbeing concepts and their corresponding measures include widely varying psychological dimensions apart from affective and cognitive aspects. Even though multidimensional wellbeing concepts are most comprehensive, none of them covers all potential wellbeing dimensions.

Ryff’s (1995) multidimensional concept of ‘psychological wellbeing’ and corresponding Scale of Psychological Wellbeing (SPWB) captures positive functioning with a focus on life span development, individuation, maturity and self-actualisation (Ryff and Keyes 1995, Ryff 1989). The scale’s unstable factor structure has attracted criticism but the particularly comprehensive concept is still used today and informs other
Chapter 2: Wellbeing: from objectivity to subjectivity

copyrightations of wellbeing. Likewise, the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) covers a comprehensive understanding of wellbeing including affective-emotional aspects, cognitive-evaluative dimensions and psychological functioning (Stewart-Brown et al. 2009). It builds on previous measures including the Affectometer, Psychological Wellbeing Scale, PANAS, Depression-Happiness Scale, and WHO-5 (Tennant et al. 2007a) and has also been used in people with severe mental illness (Margrove et al. 2012). Other multidimensional wellbeing scales include the ‘L’Echelle de Bien-Etre’ (EBE), which aims to capture variations in wellbeing following changing environmental and personal circumstances (Badoux and Mendelsohn 1994); the Mental, Physical and Spiritual Wellbeing Scale (MPSWB) which defines wellbeing as the balanced nourishment of the mind, body, and spirit (Vella-Brodrick and Allen 1995); the Life Satisfaction Index (LSI) which focuses on morale and adjustment in the elderly (McDowell 2010); and the Philadelphia Geriatric Center Morale Scale (PGCM) which equals morale with ‘generalised wellbeing’ (Lawton 1972). Table 2.1 organises these measure of multidimensional wellbeing into categories, to illustrate the variable coverage of diverse dimensions with relatively little overlap between the individual measures.

Table 2.1: Dimensions of multidimensional wellbeing scales

<table>
<thead>
<tr>
<th>Captured wellbeing dimensions</th>
<th>SPWB</th>
<th>WEMWBS</th>
<th>EBE</th>
<th>MPSWB</th>
<th>LSI</th>
<th>PGCM</th>
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<tbody>
<tr>
<td>Social</td>
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<td>interpersonal connectedness</td>
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<td>social satisfaction</td>
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<tr>
<td>interpersonal relationship</td>
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<td>competence</td>
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<td>autonomy</td>
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<tr>
<td>Psychological</td>
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<td>self-acceptance</td>
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<td>personal development</td>
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<tr>
<td>Mental</td>
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<td>clear thinking</td>
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<tr>
<td>energy</td>
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<tr>
<td>Physical</td>
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<tr>
<td>Physical health perception</td>
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<tr>
<td>Spiritual</td>
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<tr>
<td>spiritual activities</td>
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</table>
Overall, multidimensional concepts and scales capture a wide range of constructs related to wellbeing. Their breadth makes them ideal for gaining a comprehensive picture of wellbeing in research and clinical practice. However, when choosing scales for research the specific coverage of their components should be carefully considered as they potentially vary widely.

One important consideration for the choice of a specific measure is its sensitivity to change, especially when intended to assess the effect of an intervention. While most of the above mentioned scales have been extensively used in cross-sectional research, prospective studies are scarce and sensitivity to change has not been clearly established, especially for people with severe mental illness.

**Additional wellbeing concepts and measures**

Two domains are covered in some of the multidimensional wellbeing concepts and scales but usually receive relatively little attention in comparison with other aspects within multidimensional constructs. These are ‘social wellbeing’ and ‘spiritual wellbeing’, both of which may be considered as components of wellbeing, determinants of wellbeing, or separate concepts.

A prominent focus on the social domain of wellbeing can be found in relation to specific populations, such as older adults and terminally ill patients. Wellbeing concepts for these populations often include relations with family and carers (Prince-Paul 2008). However, despite the widely accepted importance of social factors also in psychological and psychiatric research and practice (Lerner 1973), there is a lack of generally applicable scales that adequately measures the social domain of wellbeing (Keyes and Lopez 2005).

This finding applies even more to the spiritual dimension of wellbeing. Notably, spirituality is absent from most psychological multidimensional wellbeing scales while prominently considered in other fields such as oncology, palliative care, or life-threatening illness (Brady et al. 1999) and in the nursing sciences (Astedt-Kurki 1995). There are at least three possible explanations for the relative neglect of the spiritual dimension within psychological wellbeing concepts. First, spirituality in a broad sense may be considered by authors to be at least partly covered by social or relational dimensions of wellbeing, e.g. belief in a higher order of things, purpose and meaning in life. Second, there may be conceptual barriers to defining spirituality and religion, especially in a cross-culturally applicable way (Hungelmann et al. 1996, Kreitzer et al.)
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2009, Gow et al. 2011). Third, there is evidence that psychology and psychiatry may be particularly reluctant to address spirituality (Huguelet et al. 2011).

**Wellbeing measures in specific populations**

Concepts and measures of wellbeing have also been adapted to specific populations and patient groups, following the rationale that specific conditions may affect wellbeing in particular ways. Examples include job related wellbeing (Van Katwyk et al. 2000), caregiver wellbeing (Gitlin et al. 2006), or wellbeing in relation to surgery (McKenna et al. 1998), or gastro-oesophageal reflux (Ducrotte and Zerbib 2007).

In the mental health field, the Subjective Wellbeing Under Neuroleptics Scale (Naber et al. 2001) has been developed to assess the subjective side-effects of antipsychotic therapy. This wellbeing measure therefore equates wellbeing with the absence of symptoms, as discussed in Section 2.2.

Similarly, cross-cultural validations have been attempted for some wellbeing scales (Lau et al. 2005, Watson et al. 1988, Diener et al. 1985), following the rationale that different cultures may e.g. attach different values to positive and negative affect (Wirtz et al. 2009), or place different emphasis on individualistic versus community orientation (Ng et al. 2003). However, overall, the cross-cultural validity of the existing mainly Western wellbeing concepts has not received significant attention so far, and wellbeing concepts for indigenous cultures are rare (Thomas et al. 2010, Kowal et al. 2007).

Overall, no multidimensional wellbeing concept covers all available wellbeing dimensions. None of the individual concepts can be regarded generally superior to others, and their utility depends on the target group they are applied to. Especially for mental health research, a suitable concept of wellbeing should be as comprehensive and theoretically and practically relevant as possible. Such exhaustive conceptualisations of wellbeing extend beyond multidimensional wellbeing concepts. Attempts to develop overarching and inclusive wellbeing concepts can be found in the integrative strand of wellbeing research, which is now outlined.

**2.4 The integrative strand of wellbeing research**

The World Health Organisation (WHO) defines health as “a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity” and mental health as “a state of wellbeing in which the individual realises his
or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community” (World Health Organisation. 2004). These highly inclusive definitions of wellbeing and mental health span both poles of the spectrum, i.e. illness or the absence thereof as well as optimum or peak states.

Researchers, mainly in the field of psychology, have devised equally comprehensive and overarching definitions of wellbeing and health, i.e. of a good life, by including components of all previously outlined approaches. While the medical and psychological strands are usually covered, the economic strand is represented to a lesser degree. This varying emphasis is partly supported by empirical research showing that the goodness of life is commonly judged by people according to happiness, meaning, and – to a lesser extent – wealth (King and Napa 1998).

Table 2.2 maps some examples of good life conceptualisations. While their constituent components widely overlap some differences also remain, e.g. physical health is only included in one definition (Ventegodt et al. 2003a, Ventegodt et al. 2003b). Differences between good life concepts may arise from their target population, e.g. Lawton’s (1983) concept is specifically developed for older people (Lawton 1983), or from their cultural background, e.g. a concept developed in Asia includes conformity with conventions (Cheung 1997) while one developed in the United States includes ‘a life dedicated to achieving for the sake of achievement’ in its dimensions of the good life, called ‘Authentic Happiness’ (Seligman. 2002). The concept of Authentic Happiness also differs from others in that it does not provide an overall definition but instead assumes the possibility of different types of good life which are not mutually exclusive but additive, and routes to which depend on the individual. These overarching definitions of the good life have no corresponding measurement tools but come with recommendations for combinations of varying published or unpublished scales for their assessment.
## Table 2.2: Components of the ‘good life’

<table>
<thead>
<tr>
<th>Components</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>wellbeing (i.e. overall feeling about one’s being)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>satisfaction with life life satisfaction</td>
</tr>
<tr>
<td>Happiness</td>
<td>happiness (i.e. existential feeling of cheerfulness and harmony) positive and negative affect pleasant life (i.e. hedonistic orientation to positive emotions and pleasures)</td>
</tr>
<tr>
<td>Meaning</td>
<td>meaning in life religious commitment meaningful life (i.e. belonging to and serving something larger than oneself)</td>
</tr>
<tr>
<td>Balance</td>
<td>biological balance of the body, reflecting overall physical health</td>
</tr>
<tr>
<td>Realise potential</td>
<td>realising life potential autonomy, self-actualising behavioural competence engaged life (i.e. optimal use of character strengths)</td>
</tr>
<tr>
<td>Meet needs</td>
<td>fulfilment of needs domain specific perceived quality of life</td>
</tr>
<tr>
<td>Observable</td>
<td>objective factors (e.g. income or marital status) objective environment</td>
</tr>
<tr>
<td>Achievement</td>
<td>achieving life (i.e. achieving for the sake of achievement)</td>
</tr>
<tr>
<td>Connectedness</td>
<td>mutual interpersonal concerns (e.g. marital satisfaction, understanding others)</td>
</tr>
<tr>
<td>Fitting in</td>
<td>conformity with conventions</td>
</tr>
</tbody>
</table>

In the integrative approach, positive mental health receives explicit attention. This added focus on the positive instead of just on deficits corresponds with the introduction of a recovery orientation in mental health research and practice as well as with the emergence of the academic discipline of Positive Psychology. Both developments provide an important context for the good life approach in relation to mental illness (Slade 2012).
However, the concept of positive mental health is also far from uniform. One proposed organisation identifies six models of positive mental health from the literature (Vaillant 2003): (i) ‘above normal’, i.e. supremely functioning, empathic, socially competent, resilient, self-actualised, future oriented, autonomous and self-aware; (ii) ‘positive psychology’, i.e. character strength, talents and enablers; (iii) ‘maturity’, i.e. reflecting theories of life time development with greater maturation reflecting better mental health, (iv) ‘social-emotional intelligence’, (v) ‘wellbeing’, i.e. happiness depending on genetic, environmental and personality factors; and (vi) ‘resilience’. This suggested classification again stresses how diverse and entangled the concepts of wellbeing and mental health are and how subjective their classification.

The Complete State Model of Mental Health is another classification proposed to provide clarity for research and practice. This conceptual framework includes both poles of mental health and wellbeing. Mental illness lies on a spectrum from absent to present. Wellbeing lies on a spectrum from low to high. Both can be diagnosed according to the number of ‘symptoms’ (i.e. dimensions) of wellbeing, mental illness and functioning a person exhibits. Wellbeing in this model is conceptualised to include all aspects summarised in the psychological approach, i.e. positive affect, satisfaction, and psychological wellbeing, according to Ryff’s (1995) comprehensive definition, and social wellbeing as an additional dimension (Keyes 2005, Keyes et al. 2010). The symptoms of wellbeing at the same time mirror symptom clusters of mental illness, supplemented with the assessment of functioning to get a fuller picture of positive and ill mental health (Keyes 2005).

This notion of a dual continuum may be particularly relevant in a mental health context, because it highlights that people can experience wellbeing at the same time as experiencing mental illness. According to the complete state model, a person may fall into one of four clusters: (i) complete health (*flourishing*), i.e. absence of recent mental illness plus high wellbeing, (ii) incomplete mental health (*languishing*), i.e. no mental illness plus low levels of wellbeing, (iii) complete mental illness (*floundering*), i.e. presence of recent mental illness plus low levels of wellbeing, and (iv) incomplete mental illness (*struggling*), i.e. presence of mental illness plus moderate to high levels of wellbeing (Keyes 2005). The complete state model of health (reproduced from Slade 2010) is depicted in Figure 2.2.
Empirical data show that measures of mental health (in this case emotional, psychological, and social wellbeing) and mental illness (major depressive episode, generalised anxiety, panic disorder, and alcohol dependence) fall into separate correlated unipolar dimensions in confirmatory factor analysis (Keyes, 2005). Furthermore, the categorical diagnoses of the complete state model proved predictive of functioning in several life domains. For example, completely mentally healthy adults showed the fewest health limitations, the fewest missed days of work, and the healthiest psychosocial functioning. Malfunctioning was greatest and positive functioning lowest among those with complete mental illness, while those languishing and struggling performed in between (Keyes 2005).

2.5 Summary and conclusion

There is substantial variation in the definition and measurement of wellbeing, and psychometric properties are not established for all proposed assessment tools. An integrative approach to the concept may best reflect its complexity and may hence be most suitable for use in mental health research and practice. The emergent understanding of wellbeing as an individual, multi-dimensional construct mirrors systematic review evidence on the recovery process (Leamy et al. 2011). The complete state model of health may best capture a recovery perspective, which assumes that people can strive to have a good life even within the limitations of
mental illness. As a conceptual background to the striving for a good life, Seligman’s (2002) model of Authentic Happiness seems promising since it allows for individually different routes towards wellbeing depending on a person’s subjective values, strength and priorities.

Limitations
The overview on wellbeing provided in this chapter is based on a comprehensive but not systematic review of the literature. It emphasises the measurable concepts of wellbeing. This focus on measures means that models of wellbeing for which no corresponding measures exist may be underrepresented.

The chapter organises the concepts of wellbeing in only one possible way. Given the vast variety of wellbeing concepts, other researchers may have structured the available material differently depending on their research background or aims. The objective of this chapter was to provide an overview on the literature to help draw conclusions and chose measures specifically for a study on wellbeing within a mental health research context.

Key knowledge gaps
Three important gaps can be identified. First, in the integrative strand of wellbeing research, reliable and valid measurement tools will need to be developed to capture outcomes consistent with the proposed models of wellbeing. Second, given the wide variety of concepts and measures, a meaningful comparison of research results focusing on wellbeing is difficult, as is the identification of determinants of wellbeing in specific populations, e.g. people with severe mental illness. A consensus definition of wellbeing for specific populations may need to be established to enable synthesis of research results for specific populations. Third, knowledge on wellbeing for people with severe mental illness is still scarce and a comprehensive concept or measurement tool for wellbeing in this population is missing.

Implications for this thesis
Improving wellbeing in people with severe mental illness is an important goal of recovery oriented mental health service provision. In order to achieve this goal, at least four necessary steps can be identified. First, a consensus definition of wellbeing, including its determinants and the processes involved in improving wellbeing, needs to be developed for people with severe mental illness. Second, the existing literature on interventions and strategies to improve wellbeing in this client group needs to be

Chapter 2: Wellbeing: from objectivity to subjectivity
systematically summarised to identify promising intervention strategies. Third, existing interventions to increase wellbeing may need to be adapted for people with severe mental illness. Fourth, suitable measurement tools for wellbeing in this client group will need to be identified, developed, or evaluated.

Before moving on to address the aims of this thesis, the next chapter will provide background information on another background area i.e.: Positive Psychology and Positive Psychotherapy.
Chapter 3: Positive psychology and positive psychotherapy

This chapter covers two areas: Positive Psychology and Positive Psychotherapy. First, Positive Psychology (PP), introduced by Martin Seligman and Mihaly Csikszentmihalyi in 1998 will be described and critiques of this “new movement” will be considered. Some other prominent positive approaches to psychology and psychotherapy that have preceded the development of PP will also be described. Second, Positive Psychotherapy (PPT), as introduced by Seligman and colleagues will be outlined. The empirical evidence for PPT will be summarised and the application of PPT in people with psychosis will be discussed.

3.1 Positive Psychology

3.1.1 Describing PP

Introduction of PP

The academic discipline of Positive Psychology (PP) developed following Martin Seligman’s 1998 presidential address to the American Psychological Association (Seligman 1999). He maintained that psychology so far had mostly addressed one of its three aims, i.e. curing mental illness, whilst largely neglecting the two other aims, i.e. helping people to lead more productive and fulfilling lives; and identifying and nurturing high talent. Consequently, Seligman dedicated his presidency at the American Psychology Association to initiating a shift in psychology’s focus towards the positive aspects of human experience, positive individual traits, and more generally the positive features which make life worth living (Seligman and Csikszentmihalyi 2000). In this context, the term ‘positive’ was only ambiguously defined as what “promises to improve the quality of life and also to prevent the various pathologies that arise when life is barren and meaningless” (p.5). This was considered to apply to the factors PP focuses on, such as hope, wisdom, creativity, courage, spirituality, responsibility, or perseverance (Seligman and Csikszentmihalyi 2000).

Since its introduction, research, opinion papers, and books have been published, and a dedicated journal called The Journal of Positive Psychology has been established. Networks, courses and research centres have been created, and sizeable amounts of money allocated to PP research, education, and training by various funders (Linley et al. 2006). PP has also received broad and international media coverage.
Definition of PP

Seligman and Csikszentmihalyi (2000) originally conceptualised Positive Psychology as a “new movement” (p. 5) in psychology. This notion of a movement was considered necessary in order to counteract the perceived powerful focus of psychology on the negative aspects of life and ill health. Positive Psychology was originally defined as follows:

*The field of positive psychology at the subjective level is about valued subjective experiences: wellbeing, contentment, and satisfaction (in the past); hope and optimism (for the future); and flow and happiness (in the present). At the individual level, it is about positive individual traits: the capacity for love and vocation, courage, interpersonal skill, aesthetic sensibility, perseverance, forgiveness, originality, future mindedness, spirituality, high talent, and wisdom. At the group level, it is about the civic virtues and the institutions that move individuals toward better citizenship: responsibility, nurturance, altruism, civility, moderation, tolerance, and work ethic (Seligman and Csikszentmihalyi 2000, p. 5)*

Alternative definitions of PP have also been suggested, such as:

*Positive psychology is the study of the conditions and processes that contribute to the flourishing or optimal functioning of people, groups, and institutions (Gable and Haidt 2005, p.104)*

*Positive psychology is about scientifically informed perspectives on what makes life worth living. It focuses on aspects of the human condition that lead to happiness, fulfilment, and flourishing (Linley et al. 2006, p. 5)*

*It [PP] is nothing more than the scientific study of ordinary human strengths and virtues. Positive psychology revisits “the average person,” with an interest in finding out what works, what is right, and what is improving . . . positive psychology is simply psychology (Sheldon and King 2001, p.216)*

A systematic review conducted in 2001 found 53 published definitions of PP spanning six core domains: (i) virtues and character strengths, (ii) happiness, (iii) growth, fulfilment of capacities, development of highest self, (iv) good life, (v) thriving and flourishing, and (vi) positive functioning under conditions of stress (Hart and Sasso 2001).
Research evidence in PP

Positive Psychology was originally conceptualised as a discipline strongly based on high quality quantitative research, such as observational studies or randomised controlled trials. This should allow the methods of natural sciences and evidence based medicine to be applied to the study of wellbeing (Seligman and Csikszentmihalyi 2000, Seligman and Steen 2005). The reliance on quantitative scientific methods was initially also used to set the Positive Psychology movement apart from earlier approaches to human flourishing, which may arguably have placed more emphasis on qualitative research (Becker and Marecek 2008a, Friedman 2008). Precursors of PP are described in more detail in Section 3.1.3.

In terms of content, today Positive Psychology serves as an umbrella term to accommodate research endeavours which started both before and after the introduction of the movement by Seligman and Csikszentmihalyi. Related research spans a diverse range of disciplines, such as education (Seligman 2009), organizational behaviour management (Martin 2004), sport psychology (Gould 2002), family medicine (Hershberger 2005), cancer care (Coyne and Tennen 2010) and brain injury rehabilitation (Evans 2011).

For example, cross-sectional and observational studies have investigated various positive emotions, such as joy, contentment, love, and gratitude, as well as other positive aspects, such as creativity, self-efficacy, optimism resilience, empathy and altruism, compassion, humour, and life satisfaction (Snyder and Lopez 2005). These have informed the creation of systematic measures of character strength and virtues (Seligman and Steen 2005). The variety of topics and areas makes it difficult to place specific research within or outside the spectrum of PP.

Among the areas of work in Positive Psychology research is the development and investigation of strategies that would make people durably happier. A range of approaches intended to promote wellbeing have been tested in intervention research, such as mindfulness therapy, forgiveness therapy, gratitude therapy and various forms of wellbeing therapy (Wood and Tarrier 2010). Some of the most promising amongst the strategies have been combined into one overall intervention manual named Positive Psychotherapy (PPT) (Seligman and Steen 2005). This intervention will be the focus of the present thesis.
3.1.2 Critiques of Positive Psychology

Along with the rapid evolution of Positive Psychology and the extensive publicity it has received, PP has also generated criticism which falls into five partly overlapping domains.

First, PP was criticised for denying or openly devaluing closely related prior work (Cowen and Kilmer 2002). Early stage publications were met with strong disapproval due to their implicit or explicit assumption that PP had newly created its constituent topics of interest (Christopher et al. 2008). In fact, there is a long history of movements and psychological schools that also attended to the positive aspects of life and many of the research topics examined in PP have been studied before. Examples include attachment, optimism, love, and emotional intelligence. Others topics in PP were less popular before and were boosted through the introduction of PP, e.g. gratitude, forgiveness, awe, inspiration, hope, curiosity, and laughter (Gable and Haidt 2005).

Second, PP was criticised for its polarising rhetoric creating a false dichotomy of a new ‘positive’ and an old ‘negative’ or ‘usual’ psychology (Held 2005, Lazarus 2003) when in fact the large majority of academic work in psychology may be considered neither positive nor negative, but neutral (Gable and Haidt 2005). In clinical practice, an exclusive focus on the positive was suspected to create a “tyranny of positive attitude” (Held 2004, p 11) preventing people from expressing negative emotions (Huta and Hawley 2010), and helping them avoid difficult but necessary therapeutic processes (La Torre 2007). Instead of artificially dividing the positive from the negative, human wellbeing may be framed as the ability to appreciate the inevitable dialectics of living and integrate these two domains (Huta and Hawley 2010).

Third, the feasibility of discriminating positive and negative variables has been contested. This criticism pertains to two areas: (i) the processes by which variables have a positive or negative effect; and (ii) the measurement of variables as either positive or negative. First, variables may not be invariably positive or negative (Lambert and Erekson 2008, Lazarus 2003). For example, research showed that dispositional pessimism can have debilitating motivational effects while defensive pessimism can help people deal with anxiety, adapt and perform better than strategic optimists. A PP intervention helping defensive pessimists to be more optimistic might deprive them of a useful coping strategy (Norem and Chang 2002). Hence, sometimes a pessimistic, i.e. negative, attitude can be more adaptive than an
optimistic, i.e. positive, one. Second, automatically assigning any variable of interest, especially emotions, to one of the two valences, positive or negative, without taking context or personality into consideration may create research results of questionable value and generalisability (Lazarus 2003).

Fourth, PP concepts were criticised for neglecting the cultural context of all human activity and reflecting the one-sided individualism of American society (McDonald and O'Callaghan 2008). Identity, virtue, or a 'good life' may have entirely different meanings in different cultures and it may be difficult to arrive at one universal definition of such concepts (Christopher et al. 2008). Similarly, research on recovery has been criticised for neglecting culture bound aspects e.g. UK values of tolerance and forbearance, and over-emphasising US values of empowerment and agency (Slade et al. 2012). Both wellbeing and recovery are linked to personal and social identity, which in turn are strongly based on personal and cultural values. Hence, applying a narrow set of values may lead to research results that are not generalisable or to the development of interventions which are not applicable even across similar populations such as US and the UK citizens.

Fifth, from a more philosophical perspective, PP has been criticised for its lack of a developed framework for investigating complex topics such as character, virtues, or happiness (Held 2005, Kristjansson 2010). Despite the repeated reference to Aristotle, ethical considerations were found largely missing (Fowers 2008). This relative lack of attention to conceptualisation and theoretical underpinnings may arise from the emphasis within PP research on empiricism.

PP has come a long way in responding to these criticisms. Pre-existing resource oriented psychological approaches and research on positively framed topics are now acknowledged (Csikszentmihalyi 2009). Statements on the perspective of PP have been adjusted to be less polarising, by redressing what is still perceived as an imbalance but focussing on “understanding the entire breadth of human experience, from loss, suffering, illness, and distress through connection, fulfilment, health, and wellbeing” (Linley et al. 2006, p 6). The potentially over-simplified division of positive and negative remains largely unresolved. More research is needed to explore why variables may be perceived as positive or negative and to develop measures allowing a more flexible assignment of valence. Contextual factors also receive increasing attention especially when it comes to creating a supportive context for interventions (George 2007). However, empirical research considering the complexities of cultural
diversity and societal problems is still scarce, and an increased emphasis on ethics and complex philosophically informed frameworks is so far merely stated as a future goal of PP (Csikszentmihalyi 2009). The increasing acknowledgement and inclusion of earlier works, e.g. from humanistic approaches, may be a first step towards creating a more differentiated and theoretically informed picture of positive emotions and states in PP (Christopher et al. 2008).

3.1.3 Precursors of Positive Psychology

The initial assertion of novelty, unique scientific underpinnings and intended cultural shift in the PP movement was disputed by researchers and therapists who had framed their work according to a positive and resource-oriented approach before. Some illustrative resource-oriented approaches to mental health are now briefly reviewed, and links with PP made explicit. The timeline in Figure 3.1 shows PP and some important preceding resource oriented schools.

Figure 3.1: Resource oriented approaches prior to Positive Psychology

![Timeline showing resource oriented approaches]

**New Thought**

New Thought is one of the early but still well-known movements that emphasised the transformational power of positive thinking. It became popular in the late 19th century together with other mind cure movements promising happiness, material success and good health, so long as people focus on and practice positive mental suggestions (Becker and Marecek 2008b). PP interventions today include exercises that aim to re-focus attention towards the positive (Seligman et al. 2006).

**Mental Hygiene**

From the beginning of the 20th century until the 1940s, the mental hygiene movement had widespread influence, particularly in the United States. Its aim was to facilitate the attainment of physical and mental health through perfect adjustment to society. It was
suggested that this be attained by developing and preserving those human values and achievements which contribute to a balanced mental life for the individual (Becker and Marecek 2008b). The attainment of perfect health, adjustment, achievement, and balance is reminiscent of the early conceptual framing of PP, as is the fact that the mental hygiene movement also focussed on education and postulated the importance of scientific studies in their field.

**Individual psychology and existential analysis**

More complex and comprehensive schools of thought attending to the positive were to follow after World War I and II. Alfred Adler founded the school of individual psychology which emphasises the healthy functions of the person. He considered the three ‘tasks of life’ to be occupation, social relationships, and love. Similar to PP, Adlerian Psychology acknowledged human strength and the potential for higher levels of mental health and wellbeing. However, in comparison with PP it more strongly stressed the social embeddedness and connectedness of the individual (Barlow et al. 2009). Similarly, Victor Frankl’s Existential Analysis and Logotherapy focus on people’s freedom and their will to have meaning, power and pleasure. This approach takes a very differentiated perspective on what constitutes meaningful pleasure and will yield fulfilment, and it explicitly warns against hedonism and materialism in the search for meaning (Victor Frankl Institute Vienna. 2012a, 2012b). Such underlying values ethics is not well developed in PP.

**Humanistic psychology and psychotherapy**

Similar to Martin Seligman, Abraham Maslow, who founded humanistic psychology in the 1950s, criticised the fact that psychology had focussed too much on negatives, illnesses and sins, instead of potentials, virtues, aspirations and psychological height (Froh 2004). He proposed that humanistic psychology should be based on the study of healthy, creative individuals and empirically investigate the lives and patterns of self-actualised persons. Maslow even used the term ‘positive psychology’. Of all predecessors, humanistic psychology bears most resemblance with PP in that they both aim to focus on what is healthy and growth oriented within people (Friedman 2008). Carl Rogers developed one of the best known humanistic psychotherapy approaches, i.e. person-centred psychotherapy. Rogers’ theory assumes that people have an inherent tendency towards growth, development, and optimal functioning. In his therapy a non-judgmental and unconditionally positive regard is adopted towards clients in order to help them realise their true positive potential (Cepeda and Davenport 2006).
Humanistic psychology was an established and active school of thought and research when PP was introduced. Rivalry between these two sub-disciplines of psychology was expressed in a wealth of opinion papers containing accusations and counter-accusations ranging from being unscientific and suffering from narcissism (Taylor 2001) to supporting neo-liberalism by aiming to maximise a persons’ individual and economic fulfilment (McDonald and O'Callaghan 2008). More moderate comments observed that there may be a difference between positive and humanistic psychology regarding their epistemological approach (i.e. logical positivism vs. positivism) and their focus on research methods (i.e. quantitative vs. qualitative) but that both traditions are closely related and based on a wealth of research activity (Friedman 2008).

**Other resource oriented therapeutic approaches**

Further contemporary resource oriented therapeutic approaches were summarised in a recent literature review (Priebe et al. 2014). These include systemic family therapy; solution focussed therapy; socio-therapy and therapeutic communities; music therapy; self-help groups and mutual support groups; peer support and consumer led services; and befriending. All of these approaches share at least some possible therapeutic strategies with Positive Psychology interventions. Examples include using the family as a resource (e.g. family therapy), focussing on strengths (e.g. solution focussed therapy), or on social relationships (e.g. befriending). The therapeutic strategies suggested by PP are outlined in detail in section 3.2.

**3.1.4 Positive psychology in (mental) health services**

Public health activities aim to prevent disease, premature death and disability in the population. Mental health problems strongly contribute to the burden of morbidity, mortality and impairment in the population and are hence an important field for public health specialists (World Health Organisation 1948). Indeed, the recent public health literature reflects a shift towards an increased focus on psychological health and wellbeing in addition to disorder and disability (World Health Organisation 2004). Reasons why such a shift may be beneficial include the high prevalence of mental health problems and the possible preventive value of fostering wellbeing for health behaviours. In practice, public health initiatives such as the Well London Alliance have been formed to improve community health, including mental health, and wellbeing (Well London 2012). Positive Psychology is among the prominently referred to sources of theory and evidence underlying their activities (DIY Happiness 2012).
In mental health services and research the strong focus on illness, symptoms, and deficits as the target for change has begun to shift towards strengths and resources only in recent decades. The World Psychiatric Association remarks in its official journal that “psychiatry has failed to improve the average levels of happiness and wellbeing in the general population” (Cloninger 2006, p.71) suggesting that the promotion of wellbeing is among the goals of the mental health system. This shift in the mental health field somewhat coincides with the consumer led recovery movement which has evolved since the 1970s and argues for a focus on wellbeing regardless of the presence of mental illness. Recovery in this context refers not to symptom remission but to people (re-)engaging in their life on the basis of their own goals and strengths, and finding meaning and purpose through constructing and reclaiming a valued identity and valued social roles (Slade 2010). The two movements, recovery and PP, may be complementary (Slade 2010, Resnick and Rosenheck 2006). They share a similar focus, but the former has so far been largely built on personal accounts, theories, and opinions with empirical research lagging behind (Slade and Hayward 2007), while the latter offers a quantitative research focus in need of defensible theories and contextual knowledge on which to base its application.

Research evidence for the application of PP to people with severe mental illness remains scarce. Existing research into flourishing in people not experiencing substantial challenges may help to understand underlying mechanisms which may also be relevant for people with severe mental illness. Applying and expanding the existing PP evidence base to a new seriously ill client group is the focus of this thesis.

3.2 Positive Psychotherapy

3.2.1 Disambiguation

This thesis deals with Positive Psychotherapy (PPT) as evolved from Positive Psychology and developed by Seligman and colleagues (2007, 2005). The aim of PPT is to increase wellbeing in its recipients (Seligman et al. 2006). It has to be distinguished from two other groups of therapeutic interventions: (i) those which share the same name, and (ii) those which share the same aim.

First, several authors proposed therapeutic interventions which they called ‘positive psychotherapy’. For example, Nossrat Peseschkian founded one positive psychotherapy approach in the 1970s which assumes that individuals have two basic capacities: to love and to know. It is a conflict-centred and resource-oriented
psychotherapy that also works with the unconscious (Cope 2009, Peseschkian et al. 2010). A second example is Milton H. Erickson’s hypnotherapy approach which he framed in a positive way, causing some authors to call his methods positive psychotherapy (Erickson 2010). A third example is a positive group therapy programme developed for cancer patients, focussing on post-traumatic growth (Ochoa et al. 2010).

Second, other therapies have aims similar to PPT, i.e. to attain wellbeing, happiness, or a good life, but they use different strategies to reach these aims. Examples include Fordyce’s (1977) ‘happiness intervention’, Fava et al’s (1998) ‘wellbeing therapy’ and Frisch’s (2006) ‘quality of life therapy’. These all offer a wellbeing or life satisfaction component but attend to troublesome issues and problems first and treat wellbeing as an add-on. This distinguishes them from PPT which has as its primary focus personal strengths, positive emotions and other positive resources to indirectly target symptoms and deficits.

3.2.2 Describing Positive Psychotherapy (PPT)

Positive Psychotherapy was developed originally for people with depressive symptoms following the hypothesis that depression can not only be treated effectively by reducing its negative symptoms but also by directly and primarily building positive emotions, character strengths, and meaning (Seligman et al. 2006). The intervention is based on Seligman’s early theory of Authentic Happiness (introduced in Section 2.4), in which a good life consists of three components: (i) positive emotions (the pleasant life), (ii) engagement (the engaged life), and (iii) meaning (the meaningful life). A fourth dimension was later added to the theory of Authentic Happiness: (iv) i.e. the achieving life defined as ‘a life dedicated to achieving for the sake of achievement’ (Seligman 2002), which has not informed the development of Positive Psychotherapy.

PPT can be applied in group and individual formats. It exists in 6-session and 14-session versions, with all exercises designed to address one or more of the three components of Authentic Happiness (Rashid 2008). An outline of the 14-session PPT content is shown in Table 3.1.
<table>
<thead>
<tr>
<th>Session</th>
<th>Content</th>
<th>Homework</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Orientation to PPT</td>
<td>Group guidelines, importance of homework, presenting problems discussed</td>
<td>Positive Introduction (tell a story of when you were ‘at your best’)</td>
</tr>
<tr>
<td>2. Character Strengths</td>
<td>Identify character strengths using Values in Action Classification of Character Strengths questionnaire, possibly with help of family and friends</td>
<td>Blessing Journal (identify three good things each night)</td>
</tr>
<tr>
<td>3. Signature Strengths</td>
<td>Identify signature strengths</td>
<td>Signature Strength Action Plan</td>
</tr>
<tr>
<td>4 Good vs. Bad Memories</td>
<td>Memories and cognitive reappraisal are discussed</td>
<td>Writing Memories (focusing on bad memories and distress)</td>
</tr>
<tr>
<td>5. Forgiveness</td>
<td>Transforming forgiveness into positive emotions</td>
<td>Forgiveness Letter (not necessarily delivered)</td>
</tr>
<tr>
<td>6. Gratitude</td>
<td>Enduring thankfulness, good/bad memories are discussed</td>
<td>Gratitude Letter and Visit</td>
</tr>
<tr>
<td>7. Mid-Session Feedback</td>
<td>Recap Signature Strengths Action Plan, Forgiveness, Gratitude, Discussion of progress</td>
<td>None</td>
</tr>
<tr>
<td>8. Satisficing vs. Maximising</td>
<td>Satisficing and Maximising are discussed</td>
<td>Satisficing (plan areas that could benefit from satisficing)</td>
</tr>
<tr>
<td>9. Hope, Optimism &amp; Posttraumatic Growth</td>
<td>Optimism, hope, and new opportunities are discussed. Growth from trauma is explored.</td>
<td>One Door Closes One Door Opens</td>
</tr>
<tr>
<td>10. Positive Communication</td>
<td>Active Constructive Responding is discussed</td>
<td>Active Constructive Responding Practice</td>
</tr>
<tr>
<td>11. Signature Strengths of Others</td>
<td>Character strengths of family are discussed</td>
<td>Family Strengths Tree</td>
</tr>
<tr>
<td>12. Savouring</td>
<td>Savouring techniques are discussed</td>
<td>Planned Savouring Activity</td>
</tr>
<tr>
<td>13. Altruism</td>
<td>Helping others is discussed</td>
<td>Gift of Time</td>
</tr>
<tr>
<td>14. The Full Life</td>
<td>Integration of positive emotions, engagement, positive relationships, meaning and accomplishment. Ways to sustain positive changes are discussed.</td>
<td>None</td>
</tr>
</tbody>
</table>

3.2.3 Theoretical background of Positive Psychotherapy

**The pleasant life**

Positive emotions are theorised to counteract the detrimental effects of negative emotions and contribute to resilience. It has been found that positive emotions and a broad thought-action repertoire may amplify each other and lead to an upward spiral of wellbeing (Fredrickson and Joiner 2002, Fredrickson 2004). This contrasts with
negative emotions and narrow thinking, which can perpetuate each other and lead to a downward spiral. The upward spiral of positive emotions and engagement is captured by the ‘broaden and build’ theory (Fredrickson and Joiner 2002, Fredrickson 2004) which forms an important theoretical foundation for exercises targeted at the pleasant life.

Positive emotions can refer to the past, the present or the future. Positive emotions about the past are theorised to include satisfaction, contentment, fulfilment, pride, or serenity. Corresponding intervention strategies in PPT include forgiveness and gratitude exercises (sessions 5 and 6). Positive emotions about the present include satisfaction derived from immediate pleasures. This is addressed with savouring exercises in PPT (session 12) that teach clients to savour experiences one usually often rushes through (e.g. eating a meal or having a shower). Positive emotions about the future include hope, optimism, faith, trust, or confidence, which are addressed using optimism and hope interventions. Suggested PPT exercises (session 9) include considering ‘closing and opening doors’ (Seligman et al. 2006).

**The engaged life**

The engaged life includes engagement, involvement, and absorption in work, intimate relations, and leisure. Flow theory forms an important basis for this part of a good life. Flow describes a psychological state that accompanies highly engaging activities when attention is completely focussed on the activity, time passes quickly, and the sense of self is lost (Namakura and Csikszentmihalyi 2005). An activity is suggested to be able to lead to the experience of flow when three conditions are met: (i) it has a clear set of goals and progress, (ii) the involved tasks have clear and immediate feedback, and (iii) the person performing it has a good balance between the perceived challenges and their own perceived skills (Namakura and Csikszentmihalyi 2005). Examples of flow activities include music, other creative activities, sports or work. Experiences of flow are theorised to directly increase wellbeing and to relieve the negative symptoms of depression (Seligman et al. 2006).

Exercises to enhance engagement and flow in PPT include helping clients identify their signature strengths e.g. by introducing themselves to the group through a story that illustrates their strengths (session 1) or completing a strengths questionnaire (session 2), and then coaching clients to cultivate their signature strengths (e.g. session 3).
The meaningful life

The third aspect of a good life involves the pursuit of meaning. This is conceptualised as using one’s signature strengths in order to belong to and serve something that one believes is bigger than the self, such as religion, politics, the community, the family or the nation. Establishing a meaningful life is intended to produce a sense of satisfaction and thereby increase happiness and reduce depression (Namakura and Csikszentmihalyi 2005). A corresponding strategy to establish meaning in PPT is the ‘Gift of Time’ exercise (session 13).

3.2.4 Model of Positive Psychotherapy

The theory underlying the assumed mechanisms of PPT maintains that humans are predisposed to attend (both cognitively and affectively) to threat alert. This is thought to confer evolutionary advantage – as earlier and more prominent awareness of threat leads to higher likelihood of survival, and a mind-set that anticipates disaster at any moment is prepared for the worst. The tendency to attend to negative experiences, such as threat, loss and trespass may explain why negative things attract human attention and memory more easily than positive ones. In consequence, humans are assumed to be biased toward the negative (Seligman et al. 2006).

The theory that depressed individuals exaggerate this natural tendency has also been proposed by other influential researchers. For example, Aaron T. Beck (1964) based his cognitive behavioural therapy (CBT) for depression on the same cognitive bias in depressed people who preferentially attend to, remember and expect the negative. Beck’s technique of cognitive restructuring explicitly questions and refutes this cognitive bias (Beck et al. 1987).

Similarly, PPT includes a number of exercises aiming to shift attention, memory, and expectations away from the negative and the catastrophic toward the positive and the hopeful. However, the focus of PPT exercises is on training and experience, i.e. external and behavioural, and less on cognitive insight. For example, the ‘blessing journal’ (session 3) aims to counteract the depressive bias by prompting clients to remember positive events. Exercises that facilitate flow are supposed to lead to an upward spiral of engagement and positive emotion; those activities increasing clients’ awareness of their signature strengths are thought to increase meaning, encouragement, motivation, and eventually successful problem solving (with the concomitant emotions of contentment, achievement and pride); and those teaching clients to respond in an active and constructive manner are intended to increase
social skills that lead to more positive feedback and likely improve relationships (Seligman and Steen 2005).

A fundamental assumption of PPT is that people have both an inherent capacity for happiness and a susceptibility to psychopathology. Clients are perceived as autonomous, growth-oriented individuals. Distressing, unpleasant, or negative states and experiences are not denied (Rashid 2008), in part they are even explicitly elicited (e.g. sessions 4, 5 or 9), but in doing so clients are encouraged to focus on positive aspects of such experiences. PPT acknowledges the importance of non-specific therapeutic factors for therapy outcomes (Chatoor and Kurpnick 2001) and requests that all exercises be delivered with warmth, empathy, and genuineness.

3.2.5 Evidence

A meta-analysis of 51 studies of positive interventions demonstrated significantly improved wellbeing and decreased depressive symptoms for people with depression (Sin and Lyubomirsky 2009). Included therapies focussed on mindfulness, positive writing, gratitude, forgiveness, or kindness. A more recent meta-analysis of 39 positive psychology randomised studies involving a total of 6,139 participants also concluded that positive psychology interventions can be effective in enhancing subjective and psychological wellbeing and reducing depressive symptoms (Bolier et al. 2013).

Several interventions successfully used single components of PPT. For example, undergraduate students writing about ‘ones best possible self’ showed increased wellbeing (King 2001), students writing about intensely positive experiences each day for only three days resulted in enhanced positive mood and decreased health centre visits for up to three months (Burton and King 2004); and students and people with neuromuscular disease keeping a blessings journal for 10 weeks also showed increased wellbeing (Emmons and McCullough 2003). Individual PPT exercises were also tested in RCTs with self-referred general population samples (Gander et al. 2012, Mongrain and Anselmo-Matthews 2012, Giannopoulos and Vella-Brodrick 2011) and mildly depressed people (Seligman et al. 2005). Comparison with no-treatment control and placebo (e.g. recording childhood memories) showed significantly positive effects of PPT exercises on happiness and reduction in depression for most exercises. Three studies showed a maintenance of the gains at six months follow-up (Gander et al. 2012, Mongrain and Anselmo-Matthews 2012, Seligman et al. 2005). Individual exercises also produced an increase in self-esteem and decrease in physical symptoms in a community sample (Sergeant and Mongrain 2011).
However, while individual exercises may produce benefits, there is also evidence for a dose-response relationship. An RCT assigning healthy individuals to receiving two, four, or six exercises over six weeks or a no-treatment control showed that those receiving two or four exercises experienced significant decreases in depressive symptoms post intervention, beyond those receiving six exercises. Maintenance of exercise use at a follow-up period of 1 year was highest in those receiving six exercises (Schueller and Parks 2012). Meta-analysis confirmed that assigning multiple and different positive activities in general is more effective than employing just one (Sin and Lyubomirsky 2009).

PPT as a package has so far been tested in at least 14 published studies involving healthy participants as well as participants with physical or mental illnesses, as summarised in Table 3.2.
Table 3.2: Published PPT evidence

<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Population</th>
<th>Recruitment from</th>
<th>N</th>
<th>Control Group(s)</th>
<th>PPT Intervention</th>
<th>Assessment Times</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy individuals and community samples</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lü (2013)</td>
<td>RCT</td>
<td>College students with high and low trait positive affect</td>
<td>College psychology class</td>
<td>34</td>
<td>No treatment</td>
<td>adapted from 6-session PPT, for 16 weeks</td>
<td>Baseline, pre-treatment</td>
<td>PPT group showed a significant increase in positive trait affect</td>
</tr>
<tr>
<td>Parks-Sheiner (2009)</td>
<td>RCT</td>
<td>University students with mild-moderate depression</td>
<td>Mass university email</td>
<td>110</td>
<td>No treatment</td>
<td>6-session PPT, for 6 weeks</td>
<td>Baseline, post-treatment, 3, 6 and 12 month follow-ups</td>
<td>Significantly improved depression in intervention group post-treatment, maintained until 6-months follow-up. Significant increase in life satisfaction in both groups post-treatment</td>
</tr>
<tr>
<td>Study 1:</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Rashid (2004)</td>
<td>RCT</td>
<td>Not stated</td>
<td>Not stated</td>
<td>65</td>
<td>Not stated</td>
<td>Readings, watching films on character strengths, writing reaction papers weekly, class room discussions and out-of-class exercises</td>
<td>Not stated</td>
<td>Significant increase in character strength in intervention compared to control group</td>
</tr>
<tr>
<td>Study 2:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Study 3:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chapter 3: Positive psychology and positive psychotherapy 52
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample</th>
<th>N</th>
<th>Treatment</th>
<th>Control</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rashid (2008)</td>
<td>RCT</td>
<td>Middle school students</td>
<td>22</td>
<td>None</td>
<td>Not stated</td>
<td>Limited description. “Substantial” change in happiness reported for the intervention group compared to control group.</td>
</tr>
<tr>
<td>Ouweneel (2013)</td>
<td>Controlled trial with self-selection to intervention or control</td>
<td>Community sample</td>
<td>311</td>
<td>No treatment</td>
<td>25 online assignments over 8 weeks, covering three areas: happiness, goal-setting and resource-building</td>
<td>Baseline, post-intervention significantly stronger increase in self-efficacy levels and positive emotions in intervention compared to control group</td>
</tr>
<tr>
<td>Goodwin (2011)</td>
<td>Uncontrolled study</td>
<td>Community sample with high anxiety scores</td>
<td>11</td>
<td>None</td>
<td>adapted from 6-session PPT, with 5 additional exercises, for 10 weeks</td>
<td>Baseline, post-treatment No significant changes in relationship functioning, relationship satisfaction, stress or anxiety</td>
</tr>
<tr>
<td>Huffman (2011)</td>
<td>RCT</td>
<td>Acute cardiovascular disease</td>
<td>30</td>
<td>Active control, i.e. mediation. Attentional control, i.e. recalling events from past week</td>
<td>8 weekly exercises, with weekly telephone calls: (1) three good things, (2) gratitude, (3) best possible self (health), (4) best possible self (relationships), (5) and (6) three acts of kindness and (7) and (8) a repeat of one component</td>
<td>Baseline, post-intervention The PPT group showed greater improvement in depressive symptoms, anxiety, happiness and health-related quality of life compared to the two control conditions post-intervention</td>
</tr>
</tbody>
</table>

**Somatic disorders**
### Mental disorders

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Referral</th>
<th>Sessions</th>
<th>Intervention Description</th>
<th>Follow-ups</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asgharipoor (2012)</td>
<td>RCT</td>
<td>Out-patients with major depressive disorder</td>
<td>Referral by therapists</td>
<td>18</td>
<td>12 weekly sessions, exercises focusing on the three domains of a good life</td>
<td>Baseline, post-intervention</td>
<td>Significant increases in happiness in both groups.</td>
</tr>
<tr>
<td>Seligman (2006) Study 1:</td>
<td>RCT</td>
<td>Mild to moderately-depressed students</td>
<td>University attended – method unclear</td>
<td>40</td>
<td>Placebo therapy, i.e. recording earliest memories</td>
<td>Baseline, post intervention, 3, 6, 12 month follow up</td>
<td>The intervention group showed a significant decrease in depressive symptoms at 6 and 12 month follow up compared to control group. No significant changes in life satisfaction.</td>
</tr>
<tr>
<td>Seligman (2006) Study 2:</td>
<td>RCT</td>
<td>Severely depressed students</td>
<td>Referred from Counselling Psychological Services at University of Pennsylvania</td>
<td>46</td>
<td>Two control groups: TAU with or without anti-depressant medication</td>
<td>Baseline, post intervention</td>
<td>The intervention group showed less depressive symptoms, better overall functioning, higher life satisfaction and happiness compared to both control groups post-intervention.</td>
</tr>
<tr>
<td>Study 3:</td>
<td>Uncontrolled study</td>
<td>Community sample with depression</td>
<td>Website self-referrals</td>
<td>50</td>
<td>None</td>
<td>Baseline, post-intervention (tested after each exercise)</td>
<td>Limited description. In the first month, 50 subscribers had baseline score indicating severe depression. After each completed the three blessings task and returned to the website approx. 14 days later, 94% were less depressed (mild-moderate depression)</td>
</tr>
<tr>
<td>Akhtar (2010)</td>
<td>Controlled trial – not stated if randomised</td>
<td>Young adults (14-20 years) with substance abuse issues</td>
<td>Alcohol and drug treatment service for young people</td>
<td>20</td>
<td>No treatment</td>
<td>Baseline, post-intervention, 6 and 12- week follow-ups</td>
<td>Significant increase in happiness, optimism and positive emotions post-intervention in intervention group, and decrease in happiness, optimism and positive emotions in control group.</td>
</tr>
<tr>
<td>Authors (Year)</td>
<td>Study Design</td>
<td>Participants</td>
<td>Setting</td>
<td>Sample Size</td>
<td>Intervention Details</td>
<td>Outcome Measures</td>
<td>Results</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
<td>-------------</td>
<td>---------------------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Cuadra-Peralta (2010)</td>
<td>Quasi-experimental, comparing PPT to existing CBT group.</td>
<td>Outpatients with depression</td>
<td>Mental health clinic in Chile</td>
<td>18</td>
<td>CBT</td>
<td>9 weekly sessions adapted from 14-session PPT</td>
<td>Baseline, post intervention</td>
</tr>
<tr>
<td>Huffman (2014)</td>
<td>Uncontrolled study</td>
<td>People with suicidal ideation or behaviours</td>
<td>Inpatient psychiatric unit</td>
<td>61</td>
<td>None</td>
<td>9 exercises, 1 each day: gratitude, strengths, acts of kindness, meaningful activities, counting blessings, best possible self, forgiveness and behavioural commitment</td>
<td>Pre and post each exercise</td>
</tr>
<tr>
<td>Kahler (2013)</td>
<td>Uncontrolled study</td>
<td>Community sample wanting to stop smoking and with low positive affect</td>
<td>self-referral from newspaper advert, radio, TV, Facebook, community events</td>
<td>19</td>
<td>None</td>
<td>Adapted from 6-session PPT, 7 weeks, plus transdermal nicotine patch for 8 weeks</td>
<td>Baseline, after each session, post-intervention, 5, 13, 23 week follow-ups</td>
</tr>
<tr>
<td>Meyer (2012)</td>
<td>Uncontrolled study</td>
<td>People with schizophrenia</td>
<td>Mental health services in the US</td>
<td>16</td>
<td>None</td>
<td>adapted from 6-session PPT, for 10 weeks, plus booster session after 16 weeks</td>
<td>Baseline, post-intervention, post booster session</td>
</tr>
</tbody>
</table>
As shown in Table 3.2, published studies on PPT have a number of limitations including potential selection bias, lack of diagnostic assessments, small sample sizes, lack of randomisation or lack of blinding. Moreover, the cultural background of clients is usually not considered although there is evidence for its differential effect on benefits (Sin and Lyubomirsky 2009). Hence, overall, research evidence for the efficacy of PPT has to be rated as preliminary but promising.

3.2.6 Application of PPT in people with psychosis

There is strong evidence that subjective wellbeing is not only a desirable outcome in its own right, but also a significant predictor of symptomatic response in the treatment of people with schizophrenia (Lambert et al. 2009, Schennach-Wolff et al. 2010) and is strongly associated with medication compliance in this group (Karow et al. 2007). However, no established structured intervention exists for increasing the subjective wellbeing of people with severe mental illnesses.

Given the evidence resulting from other client groups, PPT appears to be a promising approach for increasing wellbeing in people with severe mental illness. Preliminary evidence exists for its feasibility and potential usefulness in people with psychosis. An uncontrolled study in North Carolina (United States of America) of six-session PPT, called ‘positive living’ over 10 weeks for 16 people with psychosis showed significant increases in wellbeing, savouring beliefs, hope, self-esteem, and personal recovery scores as well as a decrease in paranoid, psychotic, and depressive symptoms (Meyer 2012). However, despite aiming to adapt the intervention for people with cognitive impairments, feedback indicated that most participants found it difficult to understand (Meyer 2012). The study did not identify any specific modifications to optimise the intervention for the client group and did not attempt to account for the social-cultural context. Given the potential importance of the cultural context for the applicability of PP paradigms (Section 3.1.2), it appears likely that Europeans, especially when they have to go through difficult times such as severe illness episodes, might not be fully appreciative of what they may perceive as an American value of aiming to always be positive. Specific adaptation for both culture and client group will likely be necessary to optimise PPT for people with psychosis in a European context.

3.3 Summary and conclusions

In summary, Positive Psychology is an evolving discipline. Among its main contributions to date are that (i) it provides a conceptual framework that can serve as
a theoretical basis for meeting the WHO goal of improving mental health and wellbeing, (ii) it promotes methodological rigour to be applied to the study of wellbeing, and (iii) it stimulates the generation of scientific evidence on mechanisms and processes of wellbeing as well as specific interventions to improve wellbeing.

One key intervention developed in Positive Psychology is Positive Psychotherapy. This therapeutic approach aims to increase wellbeing and improve symptoms by building strengths, meaning and positive emotions. It was developed to address depressive symptoms but preliminary evidence suggests it may be feasible and useful also for people with severe mental illness, such as psychosis.

**Implications for this thesis**

To optimise PPT for use with people with psychosis in England, adaptations will be necessary to (i) model the intervention processes for the specific client group, (ii) increase its understandability for people with potential cognitive impairments, and (iii) account for the local cultural context. These three objectives are addressed in this thesis and will be described in later chapters. First, to develop underpinning theory as recommended by the MRC (Craig et al. 200*), Chapter 4 will use systematic review techniques to explore the concept and measurement of wellbeing and associated interventions for people with psychosis.
Chapter 4: Conceptualising wellbeing in psychosis: systematic review and narrative synthesis

This chapter describes the first recommended research task in Stage 1 of the MRC framework for the development and evaluation of complex interventions, i.e. the systematic literature review.

4.1 Introduction to systematic review

In order to develop an intervention to increase wellbeing in people with psychosis, it is important to understand what the experience of wellbeing means for people with psychosis. Identifying potential influences on wellbeing will allow identification of promising target points for an intervention. An understanding of the change processes involved in improving wellbeing is needed for developing a testable model of the intervention. Finally, a clear and operationalised conceptualisation of wellbeing is necessary to decide on suitable measurement tools for testing the intervention.

Alongside the need for a clear conceptualisation of wellbeing, it is also important to identify the evidence base on existing psychosocial interventions which have been found to improve wellbeing in people with psychosis. This will ensure the new intervention is informed by best available evidence about approaches to improving wellbeing, and will support methodological choices relating to the evaluation of the intervention.

A systematic review and narrative synthesis of controlled trials of psychosocial interventions investigating wellbeing in people with psychosis was undertaken. The review was published (Schrank et al. 2013a), and is shown in Section 4.2. The published paper was edited in two ways for inclusion into the thesis: table and figure headings were modified to be consistent with the overall thesis, and the references were included in the overall reference list of the thesis. Otherwise, the content of the paper is shown exactly as published. The online data supplement included in the paper, is provided in Appendix 2 of the thesis.
4.2 Systematic review of wellbeing


Abstract
Wellbeing has become a prominent term in the political arena in recent years. However, in research the concept and use of wellbeing has been unclear, especially in the context of severe mental illness such as psychosis. This systematic review aims to characterise the evidence base relating to wellbeing in people with psychosis, by reviewing how wellbeing is measured, developing a new conceptual framework, and summarising empirical evaluations of psychosocial interventions to improve wellbeing.

We conducted a systematic review and narrative synthesis of controlled trials of interventions investigating wellbeing in people with psychosis. The 28 studies meeting the inclusion criteria used 20 different measures of wellbeing. Five dimensions of wellbeing emerged: non-observable, observable, proximal, distal, and self-defined. Interventions to improve wellbeing vary widely. The investigated interventions have been targeted at non-observable, observable and proximal levels, while evaluation measures span all five dimensions. This review offers an evidence based conceptual framework of wellbeing which can provide an empirical basis for organising future wellbeing research in psychosis. The review also shows that the evidence base for interventions is small and methodologically weak. Recommendations are made for choosing wellbeing measures for future research.

BACKGROUND

The term wellbeing has become popular in the political arena in recent years. Extensive work has been published on wellbeing and its determinants in the general population. In the UK the most comprehensive and prominent approach was taken by the Office of National Statistics (ONS, 2012). Overall, at least four academic phases of wellbeing conceptualisation and measurement can be identified. Economic concepts frame wellbeing in terms of national wealth, social determinants, development and general quality of life. Medical concepts of wellbeing frame it in relation to disorder and illness, i.e. health related quality of life. Psychological concepts view wellbeing in terms of subjective and mental concepts, ranging from positive affect to life span development and self-actualisation. Finally, integrative
concepts are evolving and informed by economic, medical, and psychological phases. Throughout these phases, the notion of wellbeing has shifted from a collectivist concept with objective measures, to being conceived in individualistic terms, with subjective measures and a distinct focus on positive psychology and recovery research (Schrank et al. 2013c). The latest ONS approach to national general population wellbeing reflects an economic perspective with an additional strong emphasis on subjective indicators of wellbeing, and views wellbeing in terms of three broad domains: individual wellbeing; factors directly affecting individual wellbeing; and more contextual domains (ONS 2012).

The transition from objectivity to subjectivity has led to wellbeing becoming a key concept in mental health. In particular, wellbeing is also a central component of recovery from mental illness (Slade 2009). Its importance is further supported by research showing an association between wellbeing and improved functioning, increased resilience and life satisfaction (Fredrickson and Joiner 2002), and suggesting its protective value against the onset or re-occurrence of mental illness (Schueller and Parks 2012).

So far, wellbeing research has focused on a variety of groups, including the general population across the life span and countries (Hatch et al. 2010, Jin at al. 2012, Liu et al. 2012), and groups with various disorders such as cancer (Schwarzer et al. 2006), traumatic injury (Kendall and Terry 2009), or HIV/AIDS (Mak et al. 2007). Recently there have been calls for a stronger focus on wellbeing within psychiatry (Cloninger, 2006), especially in the context of recovery (Resnick and Rosenheck 2006). Despite the increasing research focus on wellbeing, a consensus definition of wellbeing is missing (Schrank et al. 2013a). In the scientific literature the concept of wellbeing is differently and often only vaguely defined and empirical evidence is fragmented, especially when it comes to people with severe mental illness, such as psychosis (Wissing and van Eeden 2002).

The aim of this study is to characterise the evidence base relating to wellbeing in people with psychosis to (1) understand how wellbeing is measured in high quality research studies involving people with psychosis, (2) develop an organising conceptual framework for wellbeing as used in these studies, and (3) summarise the empirical evidence on psychosocial interventions aimed at improving wellbeing in people with psychosis.
METHOD

Eligibility criteria

We included randomised and non-randomised intervention studies investigating the effects of intervention compared with control on service users' wellbeing as primary or secondary outcome, available in full-text in English or German Language.

Studies were included if they used definitions of wellbeing from psychological and mental health research, i.e. those assuming at least a degree of subjectivity in the concept, ascertained by (i) standardised outcome measures of overall wellbeing according to any psychological and psychiatric definitions; (ii) single-question assessments of personal wellbeing; or (iii) scales containing a wellbeing factor or wellbeing subscale. We excluded studies that defined wellbeing: (i) as a solely economic construct (monetary measures and social indicators); (ii) as a solely physical construct (e.g. fitness, weight, heart rate or blood pressure); (iii) as lack of relapse or hospitalisation (i.e. “staying well”); (iv) as lack of psychiatric symptoms; and which used (v) non-standardised combinations of various scales purporting to represent wellbeing.

Inclusion criteria for participants were (i) aged 16-65 years; (ii) past or present diagnosis of a psychotic illness based on ICD-10 or DSM-IV or at least 70% in a mixed diagnosis sample (interpreted to be over-inclusive when the diagnostic description was unclear), and (iii) use or have used mental health services. This work was exempt from ethics review since it did not involve participants.

Data sources and search strategy

Five sources of data were used. First, we searched 11 bibliographic databases from inception to May 2012: EMBASE, MEDLINE, PsycINFO, British Nursing Index and Archive (accessed via Ovid); Applied Social Sciences Index and Abstracts, British Humanities Index, Sociological Abstracts, Social Services Abstracts, International Bibliography of Social Sciences (accessed via CSA Illumina); CINAHL (accessed via EBSCOHost); and the Cochrane library. Databases were searched using the following terms identified from the title, abstract, key words or medical subject headings: (‘wellbeing’ OR ‘wellbeing’ OR ‘wellness’ OR ‘happiness’ OR ‘happy’ OR ‘thrive$’ OR ‘flourish$’ OR ‘pleasure’ OR ‘joy’ OR ‘life ADJ1 satisfaction’ OR ‘satisfaction’ ADJ1 with ADJ1 life’ OR ‘strength$’ OR ‘blessing$’ OR ‘virtue$’ OR ‘good ADJ1 life’ OR
‘fulfilment’ OR ‘eudaimonia’ OR ‘eudaemonia’ OR ‘hedonism’) AND (‘severe mental illness$’ OR ‘severe mental disorder$’ OR ‘serious mental illness$’ OR ‘serious mental disorder$’ OR ‘chronic mental illness$’ OR ‘chronic mental disorder$’ OR ‘psychosis’ OR ‘psychotic’ OR ‘schizophrenia’ OR ‘bipolar’ OR ‘manic’ OR ‘mania’ OR ‘schizo-affective’ OR ‘schizoaffective’ OR ‘paranoid’ OR ‘paranoia’ OR ‘catatoni$’ OR ‘hebephreni$’ OR ‘disorganised’). The search terms and the use of MeSH headings were adapted for the individual databases and interfaces as needed. Second, tables of contents from three journals that were identified in the search as frequently publishing potentially relevant papers (British Journal of Wellbeing, Journal of Positive Psychology, Psychiatric Rehabilitation Journal), and two special issues on Positive Psychology and wellbeing were hand searched. Third, we searched the Grey Literature Network Service and web-sites of relevant charities in the field (Mental Health Foundation, New Economic Foundation, Young Foundation, Mind, Rethink). Fourth, eight experts with a high research profile in the field were asked to identify research on the promotion of wellbeing in people with psychosis. Finally, the reference lists of all included studies, relevant reviews and opinion papers were hand searched, as were relevant Cochrane reviews and NICE guideline reviews of RCTs for psychosis.

Data extraction and appraisal

The first 200 studies were independently rated for inclusion by two reviewers (BS, VB), achieving a concordance rate of 0.98. Disagreement was resolved by consensus. The remaining 19,137 studies were appraised by one review author (BS). Data were extracted into an Excel spreadsheet developed for a previous systematic review with narrative synthesis (Schrank, et al. 2008). The methodological quality of the included studies was assessed using the Effective Public Health Practice Project “Quality Assessment Tool for Quantitative Studies” (1998). This tool rates the extent to which bias may be present in eight different components of quantitative studies. Each of the areas is rated based on set criteria resulting in a global rating of strong, moderate, or weak.

Data analysis

Objective 1: Understand how wellbeing is measured in controlled trials with people with psychosis: We reviewed available measurement tools for wellbeing and used the results as a source of information for Objectives 2 and 3. We first descriptively listed the measures and counted the retrieved studies in which they were used (see Table
4.1). After constructing the conceptual framework (see Table 4.2), we used vote counting to assess how frequently the individual framework dimensions were included in the used measures (see Table 4.3).

Objective 2: Develop an organising conceptual framework for wellbeing and Objective 3: Summarise the empirical evidence on psychosocial interventions to improve wellbeing in people with psychosis: We used a modified narrative synthesis approach (Popay et al. 2006). Objective 2 corresponds to the first narrative synthesis stage of identifying and developing a theory. Its result is a conceptual framework of wellbeing in psychosis which then serves as the organising framework for the data synthesis for Objective 3. Data synthesis for Objective 3 maps on the narrative synthesis stages two to four.

For Objective 2 we used the measures of wellbeing from the studies meeting our inclusion criteria as the individual data units. We started from the three broad domains of wellbeing and its determinants proposed by the ONS (Beaumont 2011), i.e. comprising individual feeling of wellbeing, factors directly affecting individual wellbeing, and more contextual domains, to organise the identified concepts of wellbeing. Specifically, we plotted the content of the measures and their factors according to the ONS domains, detected common components across the scales, and grouped them into higher order constructs. In an iterative process the broad groups were split into different categories and regrouped again. This led to a refinement in the overarching domains and an increasingly differentiated picture of the individual domains’ content across the measures. The resulting conceptual framework of wellbeing in psychosis was plotted against the components of national wellbeing proposed by the ONS.

For Objective 3 we aimed to identify the specific components and therapeutic methods used in each intervention. Given the huge variety of descriptive detail in the individual publications this was not possible. Hence, we identified the broad focus of each investigated intervention and its match with the new conceptual framework domains. This was possible for all studies except for those comparing overall services with each other. For the preliminary synthesis (narrative synthesis stage 2) we grouped the interventions according to their coverage of the new conceptual framework. Vote counting was used to assess the frequency of the individual wellbeing domains being addressed in the interventions. In order to assess if there was a particular weight of evidence for certain wellbeing domains, we compared the
results between the groups. To further explore relationships between studies (narrative synthesis stage 3) we compared the outcome of studies as grouped according to study methods. We tabulated the wellbeing dimensions addressed in the interventions and those addressed in the applied scales onto each other for each study. Agreement between the concept coverage in interventions and corresponding measurement was assessed by vote counting and displayed graphically. Different patterns of agreement were put in relation with the study results. To assess the robustness of the analysis (narrative synthesis stage 4) we grouped studies according to their quality rating and compared the results within and between groups.

RESULTS

Study selection is shown in Figure 4.1.

**Figure 4.1: Flow diagram of studies included in the review**

Articles screened: 19,337
- Electronic search: 18,813
- Hand search: 524
- Expert consultation: 0

Duplicates: 8,306
- Excluded on title: 8,319
- Excluded on abstract: 2,176
- Conference presentation with no corresponding paper: 71

Potentially relevant: 465
(see Data Supplement)
- Not retrievable: 44
  - Full paper retrieved: 421
    - Articles: 272
    - For reference search: 149

Included papers: 28
- Wellbeing as primary outcome: 3
- Wellbeing as secondary outcome: 25
Objective 1: Measurement of wellbeing

The search resulted in 28 eligible articles. These used 20 measures to assess wellbeing, described in Table 4.1. together with the number of studies included in the review using them as primary or secondary outcome measures.

<table>
<thead>
<tr>
<th>Scale Name</th>
<th>Brief description of constituent factors and domains</th>
<th>Established psychometric properties</th>
<th>Primary outcome measure (N studies)</th>
<th>Secondary outcome measure (N studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective Satisfaction with Life Scale (SSLS)</td>
<td>four domains: living situation, social relationships, work, self and present life.</td>
<td>yes</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>WHOQOL-BREF</td>
<td>four dimensions: psychological wellbeing (or health), physical health, social relationships, environment; plus overall quality of life</td>
<td>yes</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Lancashire Quality of Life Profile</td>
<td>eight life domains: work, leisure, social involvement, finances,</td>
<td>yes</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Yu quality of life for mental illness scale</td>
<td>eight factors: life satisfaction, autonomy, health maintenance, family support, function, social activity, physical health, psychological wellbeing</td>
<td>no</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Short Form (SF)</td>
<td>six or eight factors depending on version: physical functioning, role limitations due to physical health problems, bodily pain, social functioning, general mental health, role limitations because of emotional problems, vitality, health perception</td>
<td>yes</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Manchester Assessment of Quality of Life (MANSA)</td>
<td>eight life domains: job, finances, friendships, leisure activities, accommodation, safety, physical health, mental health; plus general life satisfaction</td>
<td>yes</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Lehman Quality of Life Interview (LQOL)</td>
<td>eight life domains: living situation, family, social relations, leisure, work, safety, finances, physical health; plus general life satisfaction</td>
<td>yes</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)</td>
<td>five life domains: physical health, subjective feelings, leisure time activities, social relationships, general activities; plus overall life satisfaction</td>
<td>yes</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
One prominent way to assess wellbeing was with measures of health related quality of life (HRQOL). However, this was not done in a consistent way. While some authors considered the listed overall HRQOL scales as measures of wellbeing, others...
reported existing wellbeing subscales of these tools separately. HRQOL measures were also used in their original purpose, i.e. described as measures of quality of life, in addition to other scales framed to assess wellbeing.

**Objective 2: Applied conceptual framework of wellbeing in psychosis**

The analysis of the measures' content resulted in a conceptual framework of wellbeing that spans five domains: (i) non-observable; (ii) observable; (iii) proximal; (iv) distal; and (v) self-defined. These domains can be understood as four layers of proximity to the person and one additional self-defined dimension.

The **non-observable** domain refers to intra-psychic phenomena such as self-perception, mood tone, or meaning and purpose in life, which are not readily visible from outside. The **observable** domain comprises aspects of a person that are exhibited to the outside world, such as environmental mastery, resolution, or physical health. The **proximal** domain describes factors which directly and immediately affect the individual. It includes what a person has or does, e.g. various kinds of relationships, finances, or occupation. Finally, the **distal** domain encompasses contextual factors which are not under a person’s immediate influence, such as the wider environment or access to services.

In addition to the questions allocated to the above domains, some of the identified measures included a broad general question on overall wellbeing or overall life satisfaction. Such overall questions reflect an individual’s personal view on what wellbeing means to them. Hence, we defined the individual overall assessment of wellbeing as a separate **self-defined** domain.

Table 4.2 shows the framework of wellbeing in psychosis resulting from our analysis in comparison with the generic framework of national wellbeing (Beaumont 2011).
<table>
<thead>
<tr>
<th>Table 4.2: Generic ONS Framework modified for psychosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONS CONCEPTUAL FRAMEWORK</strong></td>
</tr>
<tr>
<td><strong>More contextual domains</strong></td>
</tr>
<tr>
<td>1. natural environment</td>
</tr>
<tr>
<td>2. the economy</td>
</tr>
<tr>
<td>3. governance</td>
</tr>
<tr>
<td><strong>Factors directly affecting individual wellbeing</strong></td>
</tr>
<tr>
<td>1. relationships</td>
</tr>
<tr>
<td>- general social connection</td>
</tr>
<tr>
<td>- family connection</td>
</tr>
<tr>
<td>- emotional connection</td>
</tr>
<tr>
<td>- romantic connection</td>
</tr>
<tr>
<td>2. what we do</td>
</tr>
<tr>
<td>- general activity</td>
</tr>
<tr>
<td>- professional activity</td>
</tr>
<tr>
<td>- leisure activity</td>
</tr>
<tr>
<td>3. where we live</td>
</tr>
<tr>
<td>- housing situation</td>
</tr>
<tr>
<td>- financial situation</td>
</tr>
<tr>
<td>- safety</td>
</tr>
<tr>
<td><strong>Domain 3: Observable</strong></td>
</tr>
<tr>
<td>5. health - mental and physical</td>
</tr>
<tr>
<td>- physical health and functioning</td>
</tr>
<tr>
<td>- physical self-care</td>
</tr>
<tr>
<td>- general mental health and functioning</td>
</tr>
<tr>
<td>2. participation</td>
</tr>
<tr>
<td>3. autonomy</td>
</tr>
<tr>
<td>4. success</td>
</tr>
</tbody>
</table>
Domain 4: Non-observable

1. bodily feelings/vitality
   - negative feelings: fatigue, tiredness, apathy, exhaustion
   - positive feelings: energy, pep, vitality, zest

2. affect, mood tone
   - negative affect: depression, anxiety, sadness, despair, anger
   - positive affect: feeling peaceful, happy, strong, great, terrific
   - emotional regulation

3. self-perception
   satisfaction with self, self-acceptance, self-concept, self-regard

4. self-control
   self-control, behavioural emotional control

5. life perspective
   meaning, purpose, spirituality, philosophy of life

Domain 5: Self-defined

1. overall wellbeing
2. overall life satisfaction

The ONS framework of national wellbeing addresses the whole of society (Beaumont 2011). In contrast, the framework of wellbeing modified for psychosis focuses on the individual. Consequently, it places stronger emphasis on individual dimensions while distal dimensions such as environment are less prominent.

Table 4.3 displays the scales used to measure wellbeing in the included studies according to their coverage of the domains of the applied conceptual framework of wellbeing in psychosis.
Table 4.3: Coverage of wellbeing domains of included scales

<table>
<thead>
<tr>
<th>Scale Name</th>
<th>Distal</th>
<th>Proximal</th>
<th>Observable</th>
<th>Non-observable</th>
<th>Self-defined</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHOQOL-BREF</td>
<td>X</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Yu quality of life for mental illness scale (YuQoL)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Short Form (SF)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Lancashire Quality of Life Profile (LQoLP)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lehman Quality of Life Interview (LQOL)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Social Adjustment Scale II (SAS-II)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ryff's Scales of psychological wellbeing (RSPW)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjective Wellbeing under Neuroleptics Scale (SWN)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of Life Inventory (QOLI)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjective Satisfaction with Life Scale (SSLS)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal Wellbeing Index (PWI)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Manchester Assessment of Quality of Life (MANSA)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Snaith-Hamilton Pleasure Scale (SHPS)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Scale for the Assessment of Wellbeing (SAWB)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Life Satisfaction Index (LSI)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Psychological General Wellbeing Index (PGWI)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>single question on enjoyment (ENJ)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Subjective Exercise Experiences Scale (SEES)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>single question on general life satisfaction (LS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

Overall, 15 measures included proximal, 14 observable, and 15 non-observable dimensions. Distal dimensions were only mentioned once and self-defined wellbeing was asked for in nine scales. The emphasis placed on the addressed domains varied between the measures.

Objective 3: Summarising the evidence

Our third aim was to characterise the empirical evidence on psycho-social interventions to promote wellbeing for people with psychosis. The preliminary synthesis (Popay et al. 2006) resulted in a grouping of interventions as shown in Table 4.4.
<table>
<thead>
<tr>
<th>Reference</th>
<th>wellbeing focus of intervention</th>
<th>Intervention groups</th>
<th>study design</th>
<th>quality rating</th>
<th>population</th>
<th>N</th>
<th>follow-up</th>
<th>Wellbeing measure (* primary outcome)</th>
<th>effects on wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lak et al. 2010</td>
<td>Proximal</td>
<td>Intervention: Basic Conversation Skill group with skill generalization training (SGT) Control: without SGT</td>
<td>controlled clinical trial</td>
<td>strong</td>
<td>psychosis</td>
<td>106</td>
<td>6 months</td>
<td>PWI</td>
<td>significant effect of skill training without SGT at post-treatment, but no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Ban et al. 2001</td>
<td>Proximal</td>
<td>Intervention: course in group process Control: treatment as usual (TAU)</td>
<td>controlled clinical trial</td>
<td>moderate</td>
<td>unclear</td>
<td>20</td>
<td>12 weeks</td>
<td>RSPW</td>
<td>wellbeing increased in intervention group, but no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Klein et al. 1998</td>
<td></td>
<td>Intervention: Friend’s Connection Program Control: TAU</td>
<td>controlled clinical trial</td>
<td>weak</td>
<td>dual diagnosis</td>
<td>61</td>
<td>6 months</td>
<td>LQOL</td>
<td>significant difference between groups at follow-up (significant effect of intervention)</td>
</tr>
<tr>
<td>Vreeland et al. 2006</td>
<td></td>
<td>Intervention: Group Education about illness management and treatment Control: TAU</td>
<td>RCT</td>
<td>strong</td>
<td>psychosis</td>
<td>71</td>
<td>24 weeks</td>
<td>PGWI</td>
<td>no significant changes, no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Moritz et al. 2011</td>
<td>Observable</td>
<td>Intervention: Metacognitive training group Control: TAU</td>
<td>RCT</td>
<td>strong</td>
<td>psychosis</td>
<td>36</td>
<td>8 weeks</td>
<td>WHOQOL-BREF</td>
<td>no significant changes, no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Kwon et al. 2006</td>
<td></td>
<td>Intervention: Weight management Control: TAU</td>
<td>controlled clinical trial</td>
<td>moderate</td>
<td>psychosis</td>
<td>48</td>
<td>12 weeks</td>
<td>WHOQOL-BREF</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Skrinar et al. 2005</td>
<td></td>
<td>Intervention: Weight management Control: waiting list</td>
<td>controlled clinical trial</td>
<td>moderate</td>
<td>mood or psychotic disorder</td>
<td>30</td>
<td>12 weeks</td>
<td>SF, LQOL</td>
<td>wellbeing increased in intervention group, but no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Porsdal et al. 2010</td>
<td></td>
<td>Intervention: Weight management Control: TAU</td>
<td>cohort analytic study</td>
<td>moderate</td>
<td>schizophrenia 51.9%, bipolar 8.9%</td>
<td>314</td>
<td>6 months</td>
<td>SWN</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Intervention/Control Details</td>
<td>Study Design</td>
<td>Study Type</td>
<td>Sample Size</td>
<td>Length</td>
<td>Global Outcome</td>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>--------------</td>
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<td>----------------</td>
<td>------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fardig et al. 2011</td>
<td>Illness Management and Recovery group Control: TAU</td>
<td>RCT</td>
<td>strong</td>
<td>41</td>
<td>21 months MANS A</td>
<td>no significant changes, no significant difference between the groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penn et al. 2011</td>
<td>Graduated Recovery Intervention Program Control: TAU</td>
<td>RCT</td>
<td>moderate</td>
<td>46</td>
<td>8-12 weeks RSPW</td>
<td>no significant changes, no significant difference between the groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marder et al. 1996</td>
<td>Friend’s Connection Program Control: TAU</td>
<td>RCT</td>
<td>weak</td>
<td>61</td>
<td>6 months LQOL</td>
<td>significant effect favouring intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mueller &amp; Roder 2005</td>
<td>Cognitive behavioural recreation therapy Control: General Social skills and problem solving training</td>
<td>controlled clinical trial</td>
<td>weak dual diagnosis</td>
<td>70</td>
<td>1 year SAWB</td>
<td>wellbeing improved significantly in both groups, no significant difference between groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crawford et al. 2012</td>
<td>Group art therapy or activity groups without art Control: TAU</td>
<td>RCT</td>
<td>strong</td>
<td>417</td>
<td>24 months PGWI</td>
<td>no significant difference between the groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shawyer et al. 2012</td>
<td>Acceptance-based cognitive behavioural therapy (AB-CBT) Control: Befriending</td>
<td>RCT</td>
<td>moderate</td>
<td>43</td>
<td>6 months LS, ENJ</td>
<td>life satisfaction increased significantly after AB-CBT, enjoyment increased significantly after both interventions, no significant difference between groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nathans-Barel et al. 2005</td>
<td>Animal-assisted therapy Control: TAU</td>
<td>controlled clinical trial</td>
<td>weak psychosis 100%</td>
<td>10</td>
<td>10 weeks SHPS</td>
<td>significant effect of intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Intervention</td>
<td>Control</td>
<td>Study Design</td>
<td>Effectiveness</td>
<td>Measure</td>
<td>Outcome</td>
<td>Significant?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vancampfort et al. 2011a</td>
<td>Progressive muscle relaxation single session</td>
<td>Resting session</td>
<td>RCT</td>
<td>moderate</td>
<td>psychosis 100%</td>
<td>64</td>
<td>before-after</td>
<td>SEES *</td>
<td>significant effect of intervention</td>
</tr>
<tr>
<td>Vancampfort et al. 2011b</td>
<td>Yoga or single aerobic session</td>
<td>No exercise control</td>
<td>RCT</td>
<td>moderate</td>
<td>psychosis 100%</td>
<td>40</td>
<td>before-after</td>
<td>SEES *</td>
<td>significant effect of intervention</td>
</tr>
<tr>
<td>Kam &amp; Siu 2010</td>
<td>Horticultural activity programme</td>
<td>TAU</td>
<td>RCT</td>
<td>moderate</td>
<td>psychosis 83%</td>
<td>24</td>
<td>2 weeks</td>
<td>PWI</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Huxley et al. 2001</td>
<td>Intensive case management</td>
<td>Standard case management</td>
<td>RCT</td>
<td>strong</td>
<td>psychosis 100%</td>
<td>708</td>
<td>2 years</td>
<td>LQoLP</td>
<td>no significant effect of intervention (but of treatment location)</td>
</tr>
<tr>
<td>Essock et al. 2006</td>
<td>Dual diagnosis treatment within assertive community treatment</td>
<td>Dual diagnosis treatment within standard case management</td>
<td>RCT</td>
<td>strong</td>
<td>dual diagnosis</td>
<td>198</td>
<td>3 years</td>
<td>LQOL</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Lambert et al. 2010</td>
<td>Assertive Community Treatment</td>
<td>TAU</td>
<td>controlled clinical trial</td>
<td>strong</td>
<td>psychosis 100%</td>
<td>120</td>
<td>12 months</td>
<td>SWN</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Shu et al. 2001</td>
<td>Psychiatric home care</td>
<td>Psychiatric half-way house</td>
<td>cohort analytic study</td>
<td>weak</td>
<td>psychosis 100%</td>
<td>60</td>
<td>6 months</td>
<td>YuQoL</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Dott et al. 1996</td>
<td>Crisis unit</td>
<td>Psychiatric hospital</td>
<td>cohort analytic study</td>
<td>weak</td>
<td>psychosis 68%</td>
<td>78</td>
<td>variable</td>
<td>Q-LES-Q</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Broner et al. 2004</td>
<td>Criminal justice diversion</td>
<td>Standard justice</td>
<td>cohort analytic study</td>
<td>moderate</td>
<td>dual diagnoses</td>
<td>200</td>
<td>12 months</td>
<td>LQOL</td>
<td>no significant difference between the groups at follow-up</td>
</tr>
<tr>
<td>Study</td>
<td>Methodology</td>
<td>Intervention/Control</td>
<td>Type of Psychosis</td>
<td>Duration</td>
<td>Assessment</td>
<td>Results</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>-------------------------------</td>
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<td>--------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timko et al. 1993</td>
<td>Controlled clinical trial</td>
<td>Compares facilities:</td>
<td>Moderate schizophrenia or</td>
<td>403</td>
<td>12 months LSI</td>
<td>Significant difference between facilities at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boden et al. 2010</td>
<td>Cohort analytic study</td>
<td>Before cohort ACT</td>
<td>Psychosis</td>
<td>144</td>
<td>5 years SSLS</td>
<td>No significant difference between the groups at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stanard 1999</td>
<td>Controlled clinical trial</td>
<td>Intervention: Training of controlled case managers</td>
<td>Weak psychosis</td>
<td>29</td>
<td>3 months QOLI</td>
<td>Life satisfaction increased in intervention and decreased in control group, significant difference at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schmidt-Posner and Jerell 1998</td>
<td>Cohort analytic study</td>
<td>Compares three case cohort service analytic models: PACT adaptation, study intensive broker, clinical team</td>
<td>Weak psychotic or major affective disorder</td>
<td>18 months SSLS</td>
<td>Life satisfaction was significantly lower in the PACT model at follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Most studies considered wellbeing as a secondary outcome or among several outcomes with no specified primary outcome measure. Two studies used it as one of two predefined main outcomes (Vancampfort et al. 2011a, Vancampfort et al. 2011b), and only one study (Nathans-Barel et al., 2005) used wellbeing as the single main outcome. These three studies showed significant results.

Eight interventions addressed only one domain of wellbeing: proximal (n=3); observable (n=5). All others addressed combinations of wellbeing domains: proximal and observable (n=4); proximal and non-observable (n=3); observable and non-observable (n=2); and proximal, observable and non-observable (n=1). None of the interventions addressed distal matters. All studies focusing solely on observable domains showed non-significant results, while both studies focusing on a combination of observable and non-observable dimensions (Vancampfort et al. 2011a, Vancampfort et al. 2011b) were significant. No further relationships were found between intervention focus and results.

One possible explanation for non-significant results might be that the measure in a study assesses something which was not a target of the intervention. To explore this we plotted the wellbeing dimensions addressed in the included interventions against the applied measures. Results are shown in Table 4.5.
Table 4.5: Wellbeing domain addressed by interventions and/or measurement

<table>
<thead>
<tr>
<th>Reference</th>
<th>Wellbeing domains</th>
<th>Study results for wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Distal</td>
<td>Proximal</td>
</tr>
<tr>
<td>Lak et al. 2010</td>
<td>both</td>
<td>scale</td>
</tr>
<tr>
<td>Ban et al. 2001</td>
<td>both</td>
<td>scale</td>
</tr>
<tr>
<td>Klein et al. 1998</td>
<td>both</td>
<td>scale</td>
</tr>
<tr>
<td>Vreeland et al. 2006</td>
<td>both</td>
<td>scale</td>
</tr>
<tr>
<td>Moritz et al. 2011</td>
<td>scale</td>
<td>both</td>
</tr>
<tr>
<td>Kwon et al. 2006</td>
<td>scale</td>
<td>both</td>
</tr>
<tr>
<td>Skrinar et al. 2005</td>
<td>scale</td>
<td>both</td>
</tr>
<tr>
<td>Porsdal et al. 2010</td>
<td>scale</td>
<td>both</td>
</tr>
<tr>
<td>Fardig et al. 2011</td>
<td>both</td>
<td>both</td>
</tr>
<tr>
<td>Penn et al. 2011</td>
<td>both</td>
<td>both</td>
</tr>
<tr>
<td>Marder et al. 1996</td>
<td>both</td>
<td>both</td>
</tr>
<tr>
<td>Mueller and Roder 2005</td>
<td>intervention</td>
<td>both</td>
</tr>
<tr>
<td>Crawford et al. 2012</td>
<td>intervention</td>
<td>scale</td>
</tr>
<tr>
<td>Shawyer et al. 2012</td>
<td>intervention</td>
<td>scale</td>
</tr>
<tr>
<td>Nathans-Barel et al. 2005</td>
<td>both</td>
<td>both</td>
</tr>
<tr>
<td>Vancampfort et al. 2011a</td>
<td>both</td>
<td>intervention</td>
</tr>
<tr>
<td>Vancampfort et al. 2011b</td>
<td>both</td>
<td>intervention</td>
</tr>
<tr>
<td>Kam and Siu 2010</td>
<td>both</td>
<td>both</td>
</tr>
</tbody>
</table>

scale: wellbeing domain is addressed in the scale used in this study only
both: wellbeing domain is addressed in both the intervention and the scale used in this study
intervention: wellbeing domain is addressed in the intervention investigated in this study only

There was no relationship between study results and the agreement of the investigated interventions with the respective measurement tools. Only one study (Shawyer et al. 2012) showed no overlap between the wellbeing domains addressed in the intervention and the used scale. Two studies showed complete agreement. One of these had a significant result (Nathans-Barel et al. 2005) and one had not (Fardig et al. 2011). Hence, the agreement between interventions and measurement alone did not suffice to explain different study results.

Comparing studies according to the applied trial methodology did elicit a potential relationship with results. Significant effects of the intervention were found in 16.7% of cohort analytic studies, in 40% of controlled clinical trials, and in 25% of RCTs.

To assess the robustness of our analyses we grouped studies according to their quality rating. This confirmed results with respect to the focus of the investigated interventions. There was no particular weight of evidence for a specific wellbeing...
focus as studies with any quality rating addressed a mixture of wellbeing dimensions. Comparing quality ratings among study designs also confirmed a relationship. Cohort analytic studies had weak or moderate quality only (50% each); controlled clinical trials also included strong studies (20%), apart from weak and moderate ones (40% each); and RCTs showed only moderate and strong quality ratings (50% each). Finally, there was a graded relationship between the quality rating and the significance of study results. Among the weak studies 57% were significant, among those with moderate quality 30.8%, and among strong studies none showed a significant result with respect to wellbeing.

Discussion

This review aimed to characterise the evidence base relating to wellbeing in people with psychosis. Given the complexity of the construct of wellbeing and the wide range of factors it spans, together with the vastly dissimilar use of the concept in intervention studies, meta-analysis was not possible. Instead, we conducted a narrative synthesis adapted from Popay and colleagues (2006). The results offer detailed insight into the use of the concept of wellbeing in intervention research involving people with psychosis as well as explicit practical suggestions for a potential way forward in this scientific area.

Objective 1: Measurement of wellbeing

The 28 studies included in our analysis used 20 different scales to assess wellbeing. These scales covered a wide range of conceptual backgrounds. There was no single agreed on definition or framework for wellbeing and authors did usually not state why they chose a specific scale. It is important to note that amongst the various constructs considered to constitute wellbeing by individual researchers, many also feature as strong separate constructs in the literature. We decided to include multiple constructs in our examination of wellbeing without preconceived conceptual boundaries, apart from focusing on concepts including subjectivity. Our results show that no specific concept or framework has been applicable to wellbeing research as a whole. This confirms the existing impression of wellbeing as an ill-defined concept which may currently be used as a name tag for a supposedly fashionable scientific area. The most prominent conceptual overlap was found between wellbeing and health related quality of life (HRQOL). The decision taken by individual authors of whether to consider a certain scale as a measure of HRQOL or of wellbeing appeared to be
arbitrary and was usually not justified in publications. This ambiguity of concepts is also reflected by the existing literature which shows an unresolved discourse as to how far wellbeing, HRQOL and other related constructs do overlap or even include each other (Spiro and Bosse 2000).

In order to advance wellbeing research in relation to people with severe mental illness, such as psychosis, it is important to first have a conceptual framework of wellbeing in this specific client group, which then allows us to suggest promising strategies to improve wellbeing and make an informed decision on the measurement tools to be applied in future research. Objective 2 addressed this knowledge gap.

**Objective 2: Conceptual framework**

By analysing the measurement tools applied to assess wellbeing in current research involving people with psychosis, we developed an overarching framework for wellbeing in psychosis. We identified five dimensions of wellbeing. The non-observable, observable, proximal, and distal domains are conceptualised as layers of proximity to the person ranging from intra-psychic to contextual factors. In addition the self-defined domain is based on the individual assessment of general overall wellbeing. Assessment of overall wellbeing or life satisfaction has been theorised to require respondents to reflect on their overall state of life including as many domains or components as are relevant to the respective individual (Cummins 1998). Global ratings are thought to reflect a subjective valuation since different areas of life may be valued differently by individuals (Diener et al. 1999, Ryff and Keyes 1995). Such personally relevant factors do not necessarily overlap with a given scale’s explicitly mentioned dimensions and an individual’s personal view of what wellbeing means to them may be different to any aggregate framework.

The proposed conceptual framework of wellbeing in psychosis can be clearly distinguished from the generic framework of national wellbeing developed by the ONS. Issues of inequality and social justice are not captured in the framework of wellbeing in psychosis. Instead the framework places stronger emphasis on individual rather than societal factors, and refers to a number of specific dimensions that may be particularly relevant to people with psychosis, such as mental health and functioning, but also participation, autonomy, self-perception or self-control. In the ONS framework, the domain of individual wellbeing represents the subjective part of the concept. In contrast, the new conceptual framework includes subjective experience
more pervasively. The new ‘self-defined’ domain adds an additional level of subjectivity, in that it captures a person’s overall intuitive understanding of wellbeing. The proposed framework allows inferences to be made (i) for everyday practice in mental health care, (ii) for future research especially on specific interventions aiming to improve wellbeing in people with psychosis, and for (iii) the measurement of wellbeing in such research.

In clinical practice, in order to increase wellbeing it will be important to attend to not just the observable level of a person’s wellbeing but also to the non-observable, such as personal narratives and individual meaning making, to proximal issues, such as relationships and meaningful activities, and to more distal aspects, such as the perception of and coping with societal stigma. Mental health care will need to focus not only on psychopathology and functioning but also on psychological aspects and on contextual issues. This broadening of the clinical lens has also been suggested for other recent developments and claims for mental health care such as recovery oriented practice (Slade 2009) or person centred care (Mezzich and Salloum 2007).

For research, the conceptual framework can provide a theoretical basis for targeting interventions on specific aspects of wellbeing. To successfully improve wellbeing future interventions may integrate various existing strategies that have or have not been labelled as focusing on wellbeing but which have a contribution to make. Approaches that plausibly have an effect on wellbeing include, for example, broader anti stigma campaigns to affect the distal level of wellbeing; family interventions (Bird et al. 2010), social skills training, or various forms of activation (Mazzucchelli et al. 2010) for the proximal level; health education and physical activity (Holley et al. 2011), or goal setting techniques (MacLeod et al. 2008) to affect the observable level; narrative therapy and meaning making (Wallis et al. 2011) or cognitive therapy techniques (Fava et al. 1998) for wellbeing on the non-observable level. Other therapeutic interventions, e.g. positive psychotherapy (Rashid 2008), may already target more than one wellbeing domain. In order to be applicable to people with
psychosis these interventions will need to be adapted and suitably integrated.

Some known measures of wellbeing with adequate psychometric properties were not retrieved in the review, e.g. the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (Tennant et al. 2007), the Satisfaction with Life Scale (Diener et al. 1985), or the Positive and Negative Affect Scale (Watson et al. 1988). This is most likely due to their not being used in or indexed for published intervention studies with people with psychosis. No one single measurement tool exists to simultaneously address all identified dimensions of wellbeing. Combinations of existing measurement tools should be used to cover all five framework domains.

**Objective 3: Summarising the evidence base**

Published studies on interventions aiming to increase wellbeing are very dissimilar with respect to the investigated interventions, study quality, measures, and results. Only one used wellbeing as the single primary outcome, two defined it as one of two primary outcomes. All other studies reported wellbeing as one of several secondary outcomes only. The focus of most included studies on primary outcomes other than wellbeing may explain their great dissimilarities. Eight increased participants’ wellbeing and twenty did not. Failure to show significant results may be due to a variety of reasons, such as wellbeing not being the primary outcome, but also small sample size, lengthy follow-up time, very similar intervention and control group or study quality. Study quality appears to be a particularly relevant explanations for significant results, as those with low quality were most likely to significantly improve wellbeing. This is similar to other areas of medicine and points to the necessity of conducting more carefully designed RCTs in the future.

Overall, there was no particular weight on a specific intervention focus. A mixture of types of interventions seems to improve wellbeing. Also, agreement between the wellbeing dimensions addressed in interventions and those addressed in the corresponding measurement scales was not necessary for results to be significant. The different patterns of agreement rather allow the conclusion that addressing one domain relevant for wellbeing in a given intervention may have a 'spill over' effect onto other wellbeing domains or overall wellbeing, i.e. the effects of wellbeing targeted interventions seem to go beyond their immediate targets. This points to an optimistic view regarding our ability to affect wellbeing in mental health systems. Interventions that improve domains of wellbeing in various client groups do already exist. The next
step is to adapt them for people with psychosis and integrate them into an overall wellbeing therapy.

**Strengths and limitations**

This systematic review offers the first detailed description of the state of research on wellbeing in psychosis. It draws on a broad base not only of scientific but also grey literature which increases the validity of the findings. As outcome searches are known to be difficult we also included Cochrane and guideline searches to further improve the review's reliability. We identified key knowledge gaps in relation to both the scientific design and to content of research into wellbeing in psychosis. This allows us to make suggestions for a way forward in this important area of research. The review also provides the first higher level insight into the nature of wellbeing and possible ways to improve wellbeing in clinical practice.

We excluded studies using combinations of measures considered by the authors to represent wellbeing. Overall, the choice of these scales seems arbitrary and rarely explicitly justified in published articles. Including all studies in which the authors used the term wellbeing for whatever they measured would have identified a larger but less coherent sample, which would have been more difficult to organise conceptually. The selection of measures to include in the review could have been extended. However, all decisions regarding the methods of this review were taken after conducting a detailed scoping review. We decided to take a route that would lead to the most practically useful results given the complexity, diversity and diverse quality of the available data. The heterogeneity found in how wellbeing was operationalised across measures also indicates the challenges in employing wellbeing as a useful concept.

The applied conceptual framework of wellbeing in psychosis was constructed by analysing published quantitative research and does not include the first-hand experience and opinion of those affected. Hence, it reflects the understanding of wellbeing from a research perspective but cannot serve as a comprehensive model of wellbeing in the client group. Previous research has sought to obtain views of mental health service users in order to understand complex concepts and the acceptability of different methods for their assessment (Blount et al. 2002, Crawford et al. 2011). Service user views, for example gathered though qualitative research in addition to a literature review, are needed to establish a complete picture of the meaning and components of wellbeing in psychosis. However, the conceptual framework presented
in this article provides a component for a comprehensive model. It also allows us to suggest both intervention strategies and measurement tools to adequately address wellbeing in psychosis in future research.

Our review focussed on psychosis diagnoses, and future work may include a more specific diagnostic focus (e.g. schizophrenia) to investigate the extent to which wellbeing differs across diagnostic groups within psychosis. Similarly, fully meeting Objective 3 (Summarising the evidence base) will involve more detailed characterisation and synthesis of the identified intervention studies.

*End of published paper.*

**4.3 Elaboration of published systematic review**

Some details were omitted from the published article for reasons of space. The elaborations are now presented.

**4.3.1 Elaboration of Methodology**

For Objectives 2 and 3 of the systematic review, a modified narrative synthesis approach was used following guidance on using narrative synthesis in systematic reviews (Popay et al. 2006). This methodological approach allowed for the synthesis of studies that include a wide range of research designs which are insufficiently similar to permit specialist quantitative synthesis. Some methodological details relating to the narrative synthesis were not presented in the published article and are described now.

Popay and colleagues (2006) outline four typical stages of a narrative synthesis:

- Stage 1: Identifying and developing a theory
- Stage 2: Developing a preliminary synthesis
- Stage 3: Exploring relationships within and between studies
- Stage 4: Assessing the robustness of the synthesis.

In the present systematic review, Objective 2 broadly corresponds to Stage 1. It resulted in a new conceptual framework which then served as the organising framework for data synthesis in Objective 3. Data synthesis for Objective 3 maps onto Stages 2 to 4.

A number of tools can be used in each of the narrative synthesis stages (Popay et al. 2006). The appropriateness of a specific tool depends on the nature of the data.
retrieved in the literature review. Hence, the final decision for the application of each of the tools outlined below was made in the process of the narrative synthesis.

Stage 1 is concerned with developing a theory for how an intervention works, why, and for whom. A theory is developed at an early stage of the review to inform the later synthesis. Understanding of the theory behind an intervention contributes to the interpretation of the review’s findings and helps to assess how widely applicable those findings may be. No specific tools and techniques are identified for Stage 1 but Popay and colleagues (2006) suggest that this stage may be informed by tools described for later stages. The methods applied in the present systematic review are outlined in the published paper. The theory can be presented in narrative form or as a diagram. This was done in Table 4.2 of the published paper, and is expanded on in Section 4.3.3.

In Stage 2, a preliminary synthesis can be developed in seven ways.

(1) Textual descriptions of the included studies can be used to become familiar with the studies and to begin to compare and contrast findings across them.

(2) Studies may be clustered into smaller groups. Grouping categories are likely to include study design, samples, setting and contextual variables, and the nature of the results. The groups are refined as the synthesis develops, and provide an initial identification of patterns within and across studies.

(3) Studies may be tabulated to give a visual representation of both qualitative and quantitative data. This may also be used to help identify patterns across studies, specifically with regards to study design, quality assessment, outcome measures and study results.

(4) Specifics of the intervention components or study results may be transformed into a common, e.g. numerical rubric, to develop a meaningful summary of diverse studies and a more robust assessment of the range of effects that would be anticipated from a particular intervention.

(5) Vote counting may be used to assess frequencies, e.g. of different types of results, across included studies and help produce a description of patterns across the included studies.

(6) Studies involving qualitative data may be translated, followed by the application of qualitative analysis methods. Translation addresses the issues that qualitative research studies focusing on different topics may have non-apparent conceptual overlaps while apparently similar concepts may actually be referring to different
phenomena. The translation of primary themes or concepts reported across studies helps to explore similarities and differences between different studies.

(7) Translation may be followed by thematic analysis or content analysis. Both methods provide a means of organising and summarising the findings from large and diverse bodies of research. Thematic analysis is usually developed in an inductive manner without a complete set of a priori themes to guide data extraction. By contrast, content analysis uses a priori themes to identify systematically the most important themes across multiple studies (Willig 2008).

The present systematic review used six of the seven approaches. Textual descriptions were used at the outset of the analysis in a large table format to get to know the included studies and facilitate their subsequent grouping and re-grouping. Clustering of studies occurred in an inductive manner depending on the information available from the original publications. Tabulation of studies was used repeatedly at all stages of the analysis, as shown in the tables presented in the published manuscript. Vote counting was used for study outcomes (Table 4.1). Translation of conceptual wellbeing components and content analysis were used to identify the coverage of framework components in the applied scales and the application of framework components in the investigated interventions. The method was not used to synthesise qualitative studies but to synthesise conceptual information provided in quantitative studies, additionally including relevant scale development papers.

Transformation of wellbeing components into a common rubric was considered unsuitable for the development of a conceptual framework, since a quantifiable summary was not a goal at this stage of the analysis. At later stages, where quantifiable summaries may have been helpful, transformation was not applied for two reasons. First, intervention components were often insufficiently described in the original publications to allow reliable transformation into a common rubric. Second, study results were too heterogeneous and in most studies did not include wellbeing as a primary outcome preventing transformation.

In Stage 3, relationships between the studies may be investigated in seven ways:

(1) The findings of quantitative studies may be plotted graphically.

(2) Potential moderator variables may be identified at the study level. A priori chosen moderator variables of theoretical significance to the outcome may be separately assessed by examining characteristics that vary between studies such as sample characteristics, subgroups or outcomes.
(3) A concept mapping approach (Mulrow et al. 1998) may be used if applicable, to help link multiple pieces of evidence extracted from across individual studies. This may include the use of diagrams, flow charts, tables and conceptual triangulation, and can result in a number of possible models of factors and pathways effecting on the outcome.

(4) Reciprocal translation of studies, both qualitative and quantitative, into each other by seeking a common rubric (similar to Stage 2) for salient categories of meaning can be used to examine relationships as well as to summarise results.

(5) To aid the interpretation of quantitative findings, including moderators, textual study descriptions may be used.

(6) Investigator and methodological triangulation involves analysing the data in relation to the context and disciplinary perspective in which they were produced. This method can be used to identify the extent to which heterogeneity in study results may be attributable to diverse approaches taken by different researchers.

(7) Conceptual triangulation also explores relationships between data drawn from within and between studies by conceptually portraying the results of both quantitative and qualitative studies. This approach may be particularly useful for studies which provide large amounts of qualitative information, such as implementation studies.

The present systematic review used the four of the seven approaches: Scales were plotted against framework domains (Table 4.3) and intervention components in individual studies were plotted against framework domains (Table 4.4). Potential moderators were identified and described across studies (Table 4.4). The match between addressed framework components in interventions and measurement scales was investigated as a more complex moderating variable (Table 4.5). Textual descriptions were used to aid the interpretation of findings and explore the possibilities for synthesising results at a higher level. Methodological triangulation was used by assessing the impact of study methods on the significance of study results.

Concept mapping and conceptual triangulation were not possible due to insufficient qualitative conceptual information, e.g. on intervention models, in the individual studies. Similarly, reciprocal translation was not possible due to insufficient qualitative evidence in the review.

Finally, to critically examine the strength of the evidence produced by the review, Stage 4 of the analysis assesses the robustness of the results. This can be done in
five ways according to Popay and colleagues (2006):
(1) Weighting the included studies according to their relevance and assessing the methodological quality of the most relevant ones.
(2) Including only studies that meet minimal standards of methodological adequacy and relevance to the review.
(3) Specifically summarising and presenting the methodological quality of the included studies by classifying the studies as Weak, Moderate or Good evidence.
(4) Critically reflecting on the synthesis process including the methodology of the synthesis; the evidence used; assumptions made on the part of the researchers involved in the synthesis process; discrepancies and uncertainties identified; and expected changes in methodology, technology or evidence in the time period covered by the included studies.
(5) Checking the synthesis with authors of primary studies.

The present systematic review used three of the five approaches: The methodological quality of the included studies was summarised and presented. Studies were grouped according to their methodological quality and the quality rating was investigated as a moderator of study outcome. The authors also critically reflected on the synthesis process and researcher assumptions. In addition, the new framework was compared with the pre-existing ONS framework of population wellbeing (Beaumont 2011) both in tabular and graphical form (Table 4.2 in the published paper and Figure 4.1 in this chapter) but the authors of the primary studies were not contacted.

One method of including quality assessment in Stage 4 was considered to be sufficient, and hence no weighting of studies according to quality or exclusion of low quality studies was used, especially since this would have led to a marked reduction in the number of included studies.

4.3.2 Elaboration of Methods

Data extraction
For Objective 3 of the review, data were extracted from the primary studies in tabular form into a Microsoft Excel worksheet. An additional data sheet was populated with information referring to the content of the measurement tools applied in the studies (for Objectives 1 and 2). This information was extracted from the primary studies as far as possible and supplemented with data from the original scale development papers and the scales themselves.
**Assessment of methodological quality**

As reported, the methodological quality of included studies was assessed using the Effective Public Health Practice Project (EPHPP) ‘Quality Assessment Tool for Quantitative Studies’ (EPHPP 1998). A specific problem with the applied quality rating was the criteria for rating the blinding of studies. According to the rating criteria those studies that do not mention blinding should receive a higher rating than those explicitly stating that there was no blinding. Most publications did not explicitly mention blinding of the described studies, but it could reasonably be assumed that there was none. Applying the recommended rating criteria on blinding would have resulted in lower ratings for the few studies which explicitly stated that they had not been blinded. However, these studies were generally of a higher overall quality which was also reflected in their higher reporting standards. Hence, we decided not to downgrade otherwise high quality studies (to medium quality) only due to them mentioning the fact that there was no blinding.

**4.3.3 Elaboration of Results**

*Objective 2: Conceptual framework of wellbeing in psychosis*

The differences and similarities between the ONS framework of wellbeing and the newly developed framework of wellbeing in people with psychosis are tabulated in Table 4.2 of the published paper. A visual comparison was also produced to illustrate the interconnection between the individual components within both wellbeing frameworks. This is shown in Figure 4.2.
Figure 4.2: Comparison between the ONS and the new framework of wellbeing


- Individual Well-being: People’s own assessment of their own well-being
  - What we do
  - Where we live
- Factors directly affecting individual well-being
  - Education and skills
- More contextual domains
  - Natural environment
  - The economy
  - Governance
  - Relationships
  - Health (mental and physical)

Sustainability issues over time

New framework of wellbeing in psychosis

- Self-defined: people’s own assessment of their own overall well-being
- Self-defined: people’s own assessment of their own overall well-being
- Observable
  - Participation
  - Living conditions
  - Environment
- Proximal
  - Connectedness
  - Activities
  - Autonomy
  - Success
  - Self-control
  - Positive and negative affect
  - Life perspective
  - Bodily feelings (vitality)
- Non-observable
  - Health (mental and physical)
  - Mobility
- Distal
  - Environment
  - Activities
  - Autonomy
  - Success
  - Self-control
  - Positive and negative affect
  - Life perspective
  - Bodily feelings (vitality)
Analogous to the ONS framework, the new framework of wellbeing in people with psychosis is also conceptualised in terms of layers of wellbeing components. The ONS framework is intended to apply to society as a whole. Consequently it includes a reference to fairness and sustainability. In contrast, the static framework of wellbeing in psychosis applies to individuals. Hence, while fairness and sustainability are omitted, the individual self-defined domain of wellbeing gains particular relevance.

### 4.4 Implications for the thesis

The conceptual framework developed in this chapter will from now on be referred to as the **static framework** of wellbeing, because it does not identify dynamic processes involved in improving wellbeing. It has five implications for the thesis.

First, the static framework organises components of wellbeing which are relevant for people with psychosis. This allows identification of potential target points for an intervention to increase wellbeing according to the framework domains. Distal factors may be difficult to address but factors in the non-observable, observable and proximal domains appear suitable for an intervention targeted at individuals. The question of which of the factors in these three domains are most suitable to target and how, will be further explored in the qualitative study presented in Chapter 5.

Second, to understand change processes it will be necessary to investigate the experience of wellbeing for service users and the processes involved in improving it. Therefore Chapter 5 presents a qualitative study involving people with psychosis. Semi-structured interviews with service users with psychosis will be used to elicit their experience of wellbeing and the processes involved in improving it. This will validate the static framework through triangulation from a second data source, and develop a **dynamic framework** of wellbeing to characterise the process of change in improving wellbeing.

Third, the systematic review found that amongst the included interventions there was no particular weight on any one specific wellbeing focus. Rather, a mixture of types of interventions seemed to improve wellbeing. There was also a lack of agreement between wellbeing domains addressed in the interventions and those addressed in the corresponding measurement scales of the individual studies. This indicates that addressing one domain relevant for wellbeing may have positive effects also on other wellbeing domains or on overall wellbeing. Consequently, a wide-ranging intervention addressing a broad range of wellbeing domains may be most promising for improving
wellbeing. This suggestion is also supported by meta-analysis findings which show that attending to multiple different positive activities potentially conducive to wellbeing is more effective than attending to just one (Sin and Lyubomirsky 2009).

Fourth, the systematic review demonstrated that the evidence base for improving wellbeing in people with psychosis is small, diverse and methodologically weak. Wellbeing was generally not the main target outcome of the investigated interventions, and no intervention comprehensively covered the full range of influences on wellbeing identified in the static framework. No intervention which has been used in psychosis can therefore be recommended, so modifying an intervention used with other populations is justified.

Positive Psychotherapy (PPT), as outlined in Chapter 3, addresses a wide range of important aspects of wellbeing in the static framework: (i) non-observable factors, such as positive emotions, personal strengths, gratitude, and forgiveness; (ii) observable factors, including goal setting and interpersonal skills; and (iii) proximal factors, mainly including a focus on relationships and meaningful activities. PPT has been successfully applied to several populations, including healthy people, children and people with mild and major depression (Section 3.2.5). The suitability of PPT for people with psychosis will be explored further in the qualitative research part of this thesis and reported in Chapter 5 together with recommended changes.

Fifth, the review did not capture the whole range of assessment tools for wellbeing published in the literature and described in Chapter 2. This may be due to these tools not having been used in intervention studies with people with psychosis. Therefore the static framework of wellbeing cannot fully inform the choice of the most appropriate measurement tool for evaluation of the new intervention. Following the development of a dynamic framework of wellbeing (Chapter 5), the assessment tools described in Chapter 2 may also be considered as candidate measures even if they have not yet been used in prospective research involving people with psychosis.

The following chapters of this thesis will address the development of a dynamic framework of wellbeing (Chapter 5), the suitability and adaptation of PPT for people with psychosis (Chapter 5 and Chapter 6) and the development of an intervention model using qualitative study designs and expert consultation (Chapter 6).
Chapter 5: Dynamic framework for improving wellbeing in psychosis

This chapter describes the second research task in Stage 1 of the MRC framework for the development and evaluation of complex interventions, i.e. a qualitative study for the development of theory. This evidence will inform the development of a testable model specifying the intervention, the involved processes, and the expected outcomes.

5.1 Introduction to qualitative study

This chapter describes a study with two aims, both following from the systematic review described in Chapter 4. The first aim is to validate the static framework of wellbeing through triangulation from a second data source. The second aim is to develop a dynamic framework of wellbeing, to characterise the processes of change involved in improving wellbeing. This framework will identify candidate targets for an intervention to improve wellbeing in people with psychosis.

A qualitative study using semi-structured interviews with service users with psychosis was conducted and published (Schrank et al. 2013b). The paper is shown in Section 5.2. The published paper was edited in two ways for inclusion into the thesis: table and figure headings were modified to be consistent with the overall thesis, and the references were included in the overall reference list of the thesis. Otherwise, the content of the paper is shown exactly as published.
5.2 Qualitative study on improving wellbeing in people with psychosis


Abstract

Background: Wellbeing is important for people with severe mental illness, such as psychosis. So far, no clear concept of wellbeing exists for this client group. A recent systematic review and narrative synthesis developed a static framework of wellbeing components. The present study aims to validate the static framework and to illuminate the processes by which wellbeing is experienced by people with psychosis.

Methods: Semi-structured interviews were conducted with 23 service users with psychosis exploring their experience of wellbeing. Thematic analysis was used to analyse the data employing techniques taken from grounded theory to enhance the rigour of the analysis. Respondent validation was undertaken with 13 of the 23 participants.

Results: Three superordinate categories of wellbeing were identified: current sense of self; transition to enhanced sense of self; and enhanced sense of self. In the dynamic process of improving wellbeing the current sense of self undergoes a transition to an enhanced sense of self. The four factors influencing the transition are consistent with the static framework of wellbeing, hence validating the static framework. In addition, we identified three determinants of current sense of self and seven indicators of enhanced sense of self, which represent the achievement of improved wellbeing.

Conclusions: This study provides an empirically defensible framework for understanding wellbeing in terms of determinants, influences and indicators. The influences are targets for interventions to improve wellbeing, and the indicators are outcome domains to assess the effectiveness of services in supporting wellbeing.

Background

Wellbeing has become a popular topic in recent years. Extensive research has been published on wellbeing and its determinants, focusing on a variety of groups, such as the general population across the life span and cultures (Li and Fung 2014, Carey...
2013), and people with various disorders including diabetes (Dimitraki & Karademas, 2013), pain (Kratz et al. 2013), or HIV/AIDS (Earnshaw et al. 2013). In mental health research the focus has often been on common mental disorders, such as burnout (Priebe and Reininghaus 2011), depression (Lanfredi et al. 2013, Bellani et al. 2013), or distress (Shepard and Sundermann 2013). The importance of wellbeing for mental health research and practice is supported by research showing an association between wellbeing and improved functioning, increased resilience and life satisfaction (Fredrickson and Joiner 2002), and suggesting its protective value against the onset or re-occurrence of mental illness (Schueller and Parks 2012).

Wellbeing is also important for people with serious mental illness, e.g. psychosis, especially in the context of recovery (Slade 2010, Resnick and Rosenheck 2006). In a systematic review of studies on psychosis, ‘wellbeing’ was used within a range of theoretical perspectives, with an unclear distinction from concepts such as health related quality of life, mental health, affect, life satisfaction, social adjustment, and other psychological conceptualisations (Schrank et al. 2013a). Interventions to increase wellbeing in psychosis were highly diverse and not based on a coherent framework of wellbeing. The systematic review developed a static framework of wellbeing, based on the measurement of wellbeing in research involving people with psychosis. This static framework differentiates four domains of factors relevant to wellbeing: observable (visible behaviours and characteristics); non-observable (internal emotional and cognitive processes); proximal (factors under partial individual control in the immediate physical and social environment); and distal (factors beyond individual influence, in the more distant environment), as well as a separate rating of individual overall self-defined wellbeing.

The static framework offers an empirically-defensible organising structure for wellbeing research in psychosis, but does not illuminate the processes by which wellbeing is experienced or modified in this client group. This is an important omission, since understanding processes of change will identify the most promising target points for evidence-based interventions. The aims of the present qualitative study are (1) to validate the static framework of wellbeing by applying it to a second data source for triangulation, and (2) to develop a dynamic framework of wellbeing to describe the process of changes involved in wellbeing.
Methods

Sample
A convenience sample of individuals with psychosis was recruited from community mental health teams in London in October and November 2012. We attempted to ensure diversity by recruiting individuals with a range of illness durations, gender and ethnic backgrounds. Recruitment was conducted with the goal of theoretical saturation, i.e. until additional interviews no longer led to the generation of additional categories (Willig, 2008). Inclusion criteria were 18-65 years of age, a diagnosis of psychosis, using or having used mental health services, sufficient fluency in English, and able to give informed consent.

Procedures
Participants were recruited by a nurse at a depot clinic, and from research registers of two community mental health services. Diagnosis was identified from research registers or by the recruiting nurse, and verified in person. One researcher (BS) conducted all interviews. The topic guide asked about the personal experience of wellbeing and its improvement. Follow-up prompts were used to stimulate in depth description of topics. The topic guide was iteratively adapted according to the concurrent analysis. Interviews lasted 20-70 minutes. All interviews were audio recorded, transcribed, and anonymised. All participants were contacted and invited for a re-interview (conducted by BS and SR) to validate the emergent dynamic framework. These interviews lasted up to 20 minutes, and were recorded, repeatedly listened to, and relevant sections were transcribed for inclusion in the analysis.

Analysis
We began the analysis with theoretical assumptions about wellbeing based on a previous literature review conducted partly by the researchers involved in this analysis (Schrank et al., 2013a) but without an a priori hypothesis. The analysis followed three consecutive aims: (1) to identify a conceptual framework for the experience of wellbeing in people with psychosis, (2) to test the validity of current theory on wellbeing, in particular the static framework of wellbeing, and (3) to then construct a refined and revised version of the conceptual framework identified in the current analysis.

Transcripts were coded using NVivo9, a computer software package which helps qualitative researchers to organise large volumes of data and facilitates deep levels of
analysis in complex data. The analysis is not conducted by the software but remains done by the researchers. We applied thematic analysis used a combination of inductive and theoretically driven techniques (Braun and Clarke 2006). The rigour of the analysis was enhanced by using techniques taken from grounded theory including iterative inductive coding, line-by-line coding, constant comparison, the use of memos throughout the analysis process, as well as the use of summary tables to organise clusters of topics for each participant (Willig 2008).

Themes from the first round of interviews were identified, coded, and checked for fidelity in an inductive process. This process involved iterative coding following regular inspection of the data and discussion amongst researchers, leading to an increasingly refined organisation of data into emerging thematic entities. The initial descriptive analysis stage was followed by an interpretative stage. To interpret and understand the meaning of participant's experience, we drew on a range of existing theoretical constructs. At this stage we also deductively applied the static framework of wellbeing onto the data to establish its validity. Clusters of categories were named, partly using participants' own words and partly by introducing existing formulations on higher levels of analysis. As the aim of the study was to understand a process, a coding paradigm was introduced, i.e. the emergent framework was applied to each participant to test and optimise its validity. This involved the generation of summary tables capturing the interplay between the framework categories identified for each participant. Two raters (BS and VB) independently coded transcripts, and the analysis was regularly discussed amongst the researcher team. Alternative interpretations, groupings of categories and interrelations between them were discussed, consensus reached, and the emerging framework adapted in an iterative process. The re-interviews were analysed in the same way to identify themes that confirm, contradict, or extend the framework.

Results

Sample
23 participants were interviewed, of whom 13 agreed to be re-interviewed. Characteristics of participants are shown in Table 5.1.
Table 5.1: Sociodemographic and clinical characteristics of participants (n=23)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean years, SD)</td>
<td>44.6 ± 9.3</td>
</tr>
<tr>
<td>Gender male (n, %)</td>
<td>15 (65.2%)</td>
</tr>
<tr>
<td>Time since first illness onset (mean years, SD)</td>
<td>16.5 ± 10.5</td>
</tr>
<tr>
<td>Self-reported diagnosis (n, %)</td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>15 (65.2%)</td>
</tr>
<tr>
<td>Psychosis</td>
<td>2 (8.7%)</td>
</tr>
<tr>
<td>Schizoaffective disorder/Bipolar psychosis</td>
<td>2 (8.7%)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (8.7%)</td>
</tr>
<tr>
<td>Nervous breakdown</td>
<td>1 (4.3%)</td>
</tr>
<tr>
<td>No mental health problems</td>
<td>1 (4.3%)</td>
</tr>
</tbody>
</table>

*Two participants excluded due to invalid response

Aim 1: Validation of the static framework of wellbeing

The coding framework for influences on transition to an enhanced sense of self is shown in column 2 of Table 5.2. The respondent validation identified no changes to the results.
Table 5.2: Coding framework for wellbeing

<table>
<thead>
<tr>
<th>Category 1: DETERMINANTS of current sense of self</th>
<th>Category 2: INFLUENCES on transition to enhanced sense of self</th>
<th>Category 3: INDICATORS of enhanced sense of self</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Personality</td>
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The four elements of the static framework (non-observable, observable, proximal and distal) provided an adequate organising framework to allow full categorisation of the influences on the transition to an enhanced sense of self identified by participants. This transition represents a process of enhancing wellbeing, providing independent validation of the static framework.

**Aim 2: Development of a dynamic framework of wellbeing**

Participants described wellbeing as a desirable state which needed active input to be achieved and also to be maintained. Wellbeing was tied to participants’ sense of self and involved transition from a current sense of self, described as deficient at least in
some of its aspects, towards an enhanced sense of self. The attainment of this enhanced sense of self was perceived as increased wellbeing, and attributed to the successful transition. This process followed a common pattern which forms the **dynamic framework of wellbeing**. Three superordinate categories were identified in the coding framework: Determinants of current sense of self (the participant’s starting point at any given stage of development); influences on transition to enhanced sense of self (the change process involved in improving wellbeing); and indicators of enhanced sense of self (how wellbeing is experienced by participants). Specific factors identified as implicated in the transition – the determinants, influences, and indicators – varied across individuals both in quality and quantity. These factors were linked to personal values, and the values attached to specific factors differed between people and in an individual over time. Different areas of life were associated with a differing sense of self, i.e. rather advanced stages in a specific area could coexist with poor sense of self in other areas.

Figure 5.1 shows the dynamic framework of wellbeing, illustrating the direction of change and the relationship between the three superordinate categories. It illustrates the interplay of factors on a person's trajectory towards wellbeing and the dynamic nature of the process. As soon as an enhanced sense of self has been achieved, this becomes the new current sense of self allowing further development, e.g. in other aspects of the self which are perceived as deficient, to start from there. This makes the striving for wellbeing in individuals an iterative and ongoing process, which can also suffer setbacks, e.g. in case of a psychotic relapse, and may then have to be picked up again at a lower level than before.
Category 1: Determinants of current sense of self

1.1 Personality
Personality was important for defining current sense of self. It also explained the nature of the desired enhanced sense of self and the perceived routes towards it. Personality was described as comprising character traits, personal values, strengths and interests. Values included things like having money, status symbols, a specific religious denomination, positivity, continuity, or social responsibility. Acting on strengths and interests was generally perceived as rewarding.

“I’m a writer, I’m an author, and I like it when people like my books. I feel very good when I’m writing. I like all things about that. Writing makes me feel good”. (#1)

1.2 Memories
Memories of personally important experiences shaped current sense of self. They included upbringing, country of origin, relationships, health care, and activities. Good memories could provide hope or simply be an indulgence which yields positive feelings. While negative memories may damage current sense of self, they could also yield increased motivation for change and achievement.
1.3 Health

Participants connected physical health with their current sense of self. Illness symptoms or pain had a negative impact. Obesity was a particularly prominent concern. Being connected to antipsychotic medication, obesity was perceived as frustrating, conveying a sense of powerlessness and a negative self-image. Accepting obesity required great personal effort and losing weight was amongst the most frequently mentioned wishes in order to attain enhanced sense of self.

*The problem of obesity it puts me down sometimes, it’s not good for my wellbeing. There is no way I can reduce my weight because I have to keep on with the medication, and it started making me feel very sad and disappointed* (#13)

Mental health symptoms could interfere with any important aspect of life and impair the current sense of self. They impeded transition to enhanced sense of self, e.g. by impairing concentration or motivation. Mental health symptoms were even defined as the opposite of wellbeing, especially suicidality, threatening delusions, or serious substance abuse.

*Because of the condition I just completely drop everything and I just give up and I lock myself inside for weeks and barely eat and forget to call my family, my parents, my kids, don’t even look after myself properly. Sometimes I have passed weeks without showering and my house became a big mess.* (#6)

However, one participant also reported goals of solving various world problems so as to enhance sense of self by providing meaning and self-worth.

### Category 2: Influences on transition to enhanced sense of self

The change process involved in improving wellbeing represented a “transition to enhanced sense of self”. The factors influencing the transition occurred on the four levels of the static framework: non-observable, observable, proximal, and distal.

#### 2.1 Non-observable influences

Internal change processes pertained to attitudes, future thinking, and reflection. Examples of adaptive changes in attitudes included assuming more positive thinking styles, revising self-expectations, learning to acknowledge own abilities, and engaging in downward rather than upward social comparison.

*I know they say ‘compare to despair’ but the opposite is true as well. So it’s ‘compare and be grateful for what you’ve got’.* (#21)

Future thinking (both realistic and unrealistic) can facilitate transition. While goals
provided a frame of references, an anchor for coping and achievement, dreams conveyed an imagined sense of normality and comfort, also leading to enhanced sense of self.

“If I had a job, I’d work my hardest to get to the top and be the managing director of the company, if that was possible. For me it never was possible, so it’s a dream. It’s a dream that leaves me with hope. Once you got hope, you can keep the faith.” (#4)

Reflection, for example through therapy, meditation, writing, or chatting, was deemed indispensable for the transition to an enhanced sense of self. Positive effects included insight, new perspectives, orientation and motivation, and better problem solving. It also helped to appreciate achievements, embrace limitations, and find forgiveness. Forgiveness was a particularly complex topic, susceptible to conceptual confusion and difficult to achieve, but it held the potential to relieve tension, be empowering and help to move on in life. It was deemed positive especially when construed as forgiving oneself.

2.2 Observable influences
This category comprises visible behaviours and activities, such as social interactions, support-seeking, self-care, having a treat, kindness, and spiritual practise. Re-establishing connections was challenging but an important and ultimately rewarding task. Related processes included overcoming social anxiety, practising social skills, and finding activities with other people. In particular, social interaction with non-service users seemed to facilitate transition. Proposed ways to receive support, feedback or acknowledgement were strongly tied to social contact and positive relationships, e.g. with family, mental health professionals, or in faith communities, voluntary work or other spare-time activities.

“I get reassurance from family and the doctors and that keeps my wellbeing up, you know, I feel that I’m ok, so long as I get the reassurance from people.” (#15)

Self-care included establishing a daily structure, personal hygiene, and eating regular healthy meals, but also resisting alcohol, drugs or nicotine, or monitoring one’s physical fitness and weight.

Having a treat went beyond self-care. For example, while healthy, regular eating was deemed part of self-care, indulging in the experience of good food may serve as a treat. It can be a ‘bonus’ to generate positive feelings, aid relaxation, and enliven one’s daily structure.
You can listen to a happy song, you can blast the radio on and have a nice shower and wash your hair with the radio on. You can put moisturiser on, that’s important as well. (#9)

Kindness, involving doing something for others, was perceived as rewarding, satisfying and profoundly enhancing of sense of self. Kindness, attention and care could be addressed towards anyone, but family members such as parents, children and grandchildren seemed particularly important.

I look after my grandchildren, and I help other people. I always loved to help people. (#10)

Spiritual practice, such as church, mosque, private meditation or prayer, helped enhance sense of self through a number of pathways including the establishment of sympathetic social contact and feelings of comfort, security and orientation, improving insight and supporting personality development.

Going to church I get to mix with my brethren, find people to talk to, not being on my own, listen to the lovely sermon, singing, you know, that gives me comfort. (#23)

Activities, if they matched needs and interests, also had a range of positive effects from aiding daily structure to directly increasing self-worth. Leisure activities were perceived as particularly positive when coupled with social connection. Amongst specific activities, having paid employment was most highly valued. However, most participants were long-term unemployed so volunteering was considered the second most rewarding activity.

I do voluntary work with older people. It makes me feel good that I’m doing something (#22)

2.3 Proximal influences
This category comprises factors under limited personal control, including basic needs, relationships, antipsychotic medication, psychotherapy, and mental health services and staff. Having basic needs met, including a place to live, not being hungry, and having sufficient money, was deemed essential for any positive development.

Relationships were particularly important to all participants. Supportive, validating, reciprocal relationships were ascribed a multitude of positive effects. Good relationships with family were paramount as family gave unconditional support.
“There’s no substitution for family. Family do things that friends wouldn’t do, sometimes friends initially also help you but family are always there and help you no matter what.” (#5)

Identified sources of happiness included children and grandchildren and having a partner. An intimate life partner or sex life was intensely wished for, and often considered as something essential, potentially life-changing and boosting sense of self, both by those who had already experienced intimate partnerships as well as by those who had not.

There were conflicting views about antipsychotic medication. Participants talked about rejection, ambivalence, resignation and about a process of acceptance. While medication could be vital for functioning and the basis for positive development, it may also have debilitating side effects; and being able to live without medication was amongst the main visions for an enhanced sense of self.

Psychotherapy facilitated a multitude of positive adaptations leading to enhanced sense of self. Group therapy or peer support additionally had the reassuring and identity enhancing effect of sharing problems with others who had similar experiences. Mental health services were perceived as a source of support despite possibly serious harmful effects on identity, e.g. of involuntary treatment. Specific staff members, especially those conveying a sense of connection and mutual understanding, were described as a supremely positive influence on personal development.

“She just understands me and the way she talks to me is like, she doesn’t seem like a therapist but more like a daughter. She talks to me very nicely and what I found with her, I just opened up; I never hold nothing back from her. (#11)

2.4 Distal influences

This category comprises factors beyond an individual’s influence, including societal values, economy, and environment. Societal values were described to facilitate the change process by providing options and opportunities, e.g. access to leisure activities or education.

“It’s having these opportunities to do things because when one is unwell one doesn’t see the opportunities that there are.” (#17)

More generally, societal values provided a frame of reference and a sense of order and security. The economy was especially challenging for participants, many of whom were unemployed and dependent on social welfare, e.g. disability allowance. The
economic recession was mentioned as a source of insecurity. Experiencing the environment, e.g. sunshine, a walk in the park, or even television programmes about the natural wonders of the planet, may impact positively on mood and even create a sense of serenity.

“When I see all of the beauty of nature, it makes me feel calmer inside.” (#20)

**Category 3: Indicators of Enhanced sense of self**

Seven indicators of an enhanced sense of self were identified, as shown in Figure 1.

**Good feelings** or happiness in general were most frequently mentioned indicators of an enhanced sense of self. Naming specific positive emotions was often difficult, but participants mentioned comfort, solace, calmness, relaxation, peace of mind, contentment and serenity. Positive bodily feelings, such as feeling well after exercise or feeling attractive, also indicated improved wellbeing, as did having fun.

**Symptom relief** was discussed by all participants as profoundly tied to enhanced sense of self. It was often seen as the basis of wellbeing, or even as a basis of life. If symptoms remained then improved coping was essential.

“You’re not letting the voices or paranoia control you, you’re doing what you want to do. Wellbeing to me is, even if you’re paranoid you still get on and do things.” (#22)

Feeling **connected** with others, being a valued part of a relationship or group, and especially feelings of love amplified the sense of self.

When there are people asking for my service that makes me feel good, makes me feel worthwhile, and I get more connected with people from the project I am doing. These people need me and I have to provide for them. So there is this attachment, a strong bond which connects us. (#3)

Having **hope** and optimism was described as a further fundamental indicator of enhanced sense of self. Hope was not only an important outcome, but also a trigger for further positive developments, a force that kept people going despite potential setbacks.

“If you have hope you know you have a future, and only then your life has value.” (#19)
Self-worth was characterised as feeling whole, a positive self-image, self-acceptance, self-esteem, self-confidence, a sense of achievement, satisfaction, and a sense of normality.

“When you’ve done your best and you’re happy with it and you have accepted who you are and where you are going in life.” (#14)

Empowerment was described as a sense of self-determination, control and freedom, as having inner strength, agency, and being able to do what is important in life.

“Wellbeing for me means doing things as an autonomous individual.” (#7)

Having meaning in life was described as having a frame of reference, e.g. a valued societal role or religion.

“I’m a representative for the low support unit […] It makes me feel good doing it, I feel a sense of comfort and purpose when I’m doing it because I’m not only doing it for me, I’m doing it for other people. Other people who don’t want to speak, I can speak on their behalf. I convey it back to the council and see if we can come up with some suggestions that might help.” (#12)

Discussion

This study found that the process of improving wellbeing in people with psychosis was strongly tied to sense of self. Current sense of self was determined by three influences: personality, memories, and health. Improving wellbeing was an ongoing process in which the current sense of self undergoes a transition towards an enhanced sense of self. Influences that impact on this transition could be categorised according to the domains of the static framework of wellbeing: observable, non-observable, proximal, and distal (Schrank et al. 2013a). Participants described an enhanced sense of self as equivalent to improved wellbeing. The indicators of enhanced sense of self comprised good feelings, symptom relief, connection, hope, self-worth, empowerment, and meaning. The enhanced sense of self may then facilitate transition in other areas in an iterative fashion. Factors involved in the process varied in quality and quantity, both across individuals and over time.

Aim 1: To validate the static framework of wellbeing

Factors influencing transition to enhanced sense of self were consistent with, and therefore validated, the static framework of wellbeing. The place of the static framework as an organising structure for influences on the transition illustrates the previously identified challenge of defining the concept (Schrank et al. 2013c). The
static framework is based on assessment measures for wellbeing. These tools often contained items which conflated factors that influence wellbeing and wellbeing itself. For example, the latest measure of population wellbeing developed by the Office of National Statistics in the UK includes wealth in combination with economic, social and environmental factors (Self et al. 2012). Other recent concepts of wellbeing have combined what would be both influences on and indicators of wellbeing according to the results of our study, such as the PERMA model of individual wellbeing which contains positive emotions, engagement, relationships, meaning and accomplishment (Seligman 2011).

None of the existing measurement tools or interventions to improve wellbeing described in the literature span all possible influences on wellbeing (Schrank et al. 2013a). Interventions to improve wellbeing have been tested in various client groups. These have focussed on one of the influences, such as neighbourhood economic status (Ludwig et al. 2012), or physical exercise (Gademan et al. 2012), or on specific combinations of some influences such as physical and activity, health behaviour, and social engagement (Clare et al. 2012).

Aim 2: To develop a dynamic framework of wellbeing
The dynamic framework indicates that conducive circumstances and personal effort can lead to an upward spiral of positive development and continuously increased wellbeing. A similar upward spiral has been found for the beneficial effect of positive emotions and a broad thought-action repertoire which may amplify each other to counteract the detrimental effects of negative emotions and contribute to resilience (Luthans et al. 2007). While an upwards spiral is certainly not without a ceiling, especially given the likelihood of setbacks in the context of severe mental illness and the potential existence of areas resistant to positive change, the conceptualisation of wellbeing in the dynamic framework provides a strengths and resource oriented supplement to deficit-oriented approaches in mental health care. This places the framework in the context of resource oriented approaches and Positive Psychology (Waterman 2013).

Substantial overlap exists between different positively oriented concepts (Caprara et al., 2010). Conceptual overlaps exist between wellbeing and other concepts describing a good life, including quality of life, personal growth, self-actualisation, or life satisfaction (Schrank et al. 2013c). Similarly, different positively framed, i.e. resource oriented, therapy models use overlapping types of resources, such as social
relationships, strengths, self-actualisation techniques or recreational activities (Priebe et al. 2013). In practise, using specific positive approaches may well have a spill-over effect on additional positive outcomes besides the explicitly targeted one (Schrank et al. 2013a). However, more conceptual work may be needed to analyse overlapping positive intervention models and their overlapping outcomes (Priebe et al. 2014).

Most prominently, the concepts of wellbeing and recovery do overlap (Amering 2012). For example, recovery processes identified in a systematic review were connectedness, hope, identity, meaning, and empowerment (Leamy et al. 2011). These recovery processes mirror the indicators of enhanced self. However, the indicators in the dynamic framework in addition include symptom relief and, most prominently, good feelings. Wellbeing is also frequently mentioned as an important goal of recovery orientation in service provision (Slade et al. 2012, Le Boutillier et al. 2011). This suggests a conceptual convergence of recovery and wellbeing. The two approaches may ultimately coincide when both are applied effectively. If the aim of mental health services is to support recovery, then this may involve a re-orientation towards mainstream sources of wellbeing. From a recovery perspective, it has been argued that mainstream solutions should be preferred over specialist solutions to mainstream problems (Slade 2012). For example, supported exposure to social environments is preferable to social skills training for people who want more friends. By analogy, everyday sources of wellbeing – such as employment, friendship, exercise, sex, or prayer – are as important for people experiencing psychosis as for any other group in society. This is consistent with the ‘Transcendent principle of personhood’ – “people with severe mental illness are people” (Anthony 2004). Emphasising commonality in sources of wellbeing between people with and without psychosis may be more helpful than identifying diagnosis-specific sources of wellbeing.

**Clinical implications**

The four dimensions of influences on the transition can serve to identify targets for clinical interventions to improve wellbeing in people with psychosis. Distal influences, such as socio-economic status or green areas, have been shown to impact on wellbeing and mental health service use (Curtis 2007, Losert et al. 2012), but they will be the focus of population level interventions rather than mental health services. Feasible interventions exist for the remaining three dimensions. Proximal influences may be addressed through promoting recovery orientation in care teams (Slade et al.
systemic therapies focusing on family relations (Gottlieb et al. 2012), supporting social networks (Sundermann et al. 2013, Gayer-Anderson and Morgan 2012), or interventions to help meet basic needs (Fisher and Elnitsky 2012). Observable influences may be targeted using goal setting interventions (Le Boutillier et al. 2011), or relaxation techniques (Vancampfort et al., 2013). Using interventions in a group format may further support the application of observable influences such as social interaction, mutual support or kindness. Non-observable influences may be addressed through cognitive behavioural and related therapeutic approaches such as mindfulness (Langer et al. 2012), acceptance and commitment therapy (Pull 2009), or schema therapy (Masley et al. 2012), as well as humanistic approaches which focus on finding meaning.

The fact that our purposive sampling strategy led to a heterogeneous sample of people with a long history and a large standard deviation of onset of illness, means that our results are likely generalizable to a diverse clinical population of people with psychosis. It also stresses the importance of acknowledging individual differences, as not all factors will equally apply to every client with psychosis. Our findings support the assumption that focusing on a specific set of influences is likely to be unsuitable for any heterogeneous groups of people (Purgato and Adams 2012). More flexible, values- and interest-based interventions are most likely to be successful. The importance of attending to individual values in the treatment of people with mental disorders has been widely acknowledged (Barbui and Cipriani 2011). Given the variability of individually important influences for wellbeing, a flexible approach focusing on strengths and positive experiences may be most promising.

An understanding of how adaptive processes unfold that lead to improved wellbeing is clinically important. This paper focused on the development of an overall framework to describe the dynamics of wellbeing in people with a diagnosis of psychosis. The next stage of research will involve the development of a detailed understanding of the identified change process. This will require qualitative research involving people who currently undergo or have recently undergone changes in wellbeing (Carey et al. 2007). Promising theoretical bases exist for understanding change processes, such as cognitive behavioural theory (Bandura 1977) or Perceptual Control Theory (Carey 2011). Further investigation of change processes in relation to wellbeing may also be possible as part of the process evaluation of an intervention aiming to increase wellbeing in this client group.
Research implications

Interventions that target influences on the transition have been variably tested in people with psychosis. Currently, no structured intervention exists for this client group which is directed at a combination of influences and explicitly targets wellbeing. Positive Psychotherapy (PPT) is an intervention which simultaneously addresses a number of influences on the transition in order to improve wellbeing with promising results in healthy people and those with mild and common mental disorders (Rashid, 2008). It focuses on individual strengths and positive experiences and provides a framework that allows for flexibility to work on individually relevant and valued influences on wellbeing. PPT may be a promising candidate intervention to also improve wellbeing in people with psychosis. The specific adaptation and evaluation of PPT in people with psychosis should be a target for future research.

This study provides an empirically defensible framework for understanding wellbeing in terms of determinants, influences and indicators. The influences are targets for interventions to improve wellbeing, and the indicators are outcome domains to assess the effectiveness of services in supporting wellbeing.

End of published paper.

5.3 Elaboration of published qualitative study

Three important aspects were not reported in full in the paper for reasons of space, and are now further elaborated: Design rationale (Section 5.3.1), Methods (Section 5.3.2) and Results (Section 5.3.3).

5.3.1. Elaboration of design rationale

As outlined in Chapter 1, this thesis uses both qualitative and quantitative research techniques within the MRC framework for developing and testing complex interventions (Craig et al. 2008). This section provides an overview of qualitative research methodologies and the rationale for using qualitative techniques in research in general, and in this project in particular.

Qualitative research can overall be characterised by the types of questions it aims to address, which are usually concerned with meaning and people's experiences. These contrast with the focus on proportions or cause-effect relationships found in most quantitative research. Qualitative research helps to identify and describe phenomena
and processes, but cannot test hypotheses (Willig 2008). Given that the aim of this chapter is to understand a subjective process and its determinants, but not to quantify influences or outcomes, it is appropriate to apply qualitative research methods.

**Epistemology**

Qualitative research approaches, i.e. the methodologies or traditions of qualitative investigation, are held to be informed by the researcher’s epistemological position which may range between naïve realism and extreme relativism. Naïve realism assumes that observed phenomena directly reflect reality, while extreme relativism rejects concepts such as objective truth or knowledge altogether.

For quantitative research, an orientation towards empiricism and hypothetico-deductivism is usually implicitly assumed. In qualitative research, more explicit attention is paid to the researcher’s epistemological position since this will directly inform both the research questions that can be answered and the methods that can be used. Most importantly, the theoretical framework adopted by a researcher influences the results and conclusions of the research process in qualitative research. This highlights the importance of reflexivity, not only about the researcher’s personal background and its influence on the research process, but also about the epistemological background and its implications. It is beyond the scope of this chapter to explore philosophical positions in qualitative research in more depth.

Despite the potentially fundamental differences between qualitative research traditions, they all draw, to varying degrees and with adaptations, on a pool of methods or techniques for data collection and data analysis. Some of the most widely used techniques are now outlined.

**Data collection**

The standard ways of collecting data in qualitative research include semi-structured interviews, in-depth interviews, focus groups, participant observation, diaries, new media and visual data sources.

*Semi-structured interviews* are widely used because they are compatible with several methods of data analysis and relatively easily manageable compared to other data such as those generated through participant observation. In semi-structured interviews the researcher retains the control over the conversation by following the topic guide, whilst allowing the participants a degree of control to redefine the topic.
and explore novel strands of insight (Willig 2008).

*In-depth interviews* also use topic guides but these are usually shorter and less directive than for semi-structured interviews. They leave ample space for the open exploration of participants’ views and shift the control over the conversation content more to the participant than semi-structured interviews. The researcher focuses on listening and understanding while keeping the research question in mind (Bauer and Gaskell 2005).

*Focus groups* are another well-established qualitative research method in health sciences (Conrad 1990). Focus groups use the interaction amongst participants as a source of data. Participants have the opportunity to discuss in the group with other people who share similar experiences or characteristics. The group setting produces a synergistic effect by stimulating reflection and the exchange of opinions, attitudes and ideas. This effect may also make it easier to talk about difficult or controversial issues or express critiques. Focus groups can be used to facilitate the development of consensus or creative solutions to problems, or to support the joint construction of meaning. The researcher moderates the process but the control lies with the participants. The influence that the researcher might exert on the interview process can be minimized by the group interaction (Bauer and Gaskell 2005).

Data collection for interviews and focus groups usually involves audio recording and subsequent transcription. The level of detail that enters transcription depends on the research question and plans for the subsequent data analysis. For example, if the research is interested in the subtleties of communication then not only are the words transcribed but also the way in which they are spoken, e.g. pauses, interruptions, intonation, or volume of speech. If the research is only interested in the content of the interview, such non-linguistic features are not usually captured in the transcript (Willig 2008).

In the analysis of interview or conversational data in general it is important to be aware of linguistic variability, i.e. an understanding needs to be created about what the participants meant irrespective of what words they chose to say it. In the data collection phase this can be achieved by establishing good rapport with interviewees, posing flexible follow-up questions, and by taking the context of the participants and the interviews into account. In the corresponding data analysis, understanding can then be established at an interpretative analysis level (Willig 2008).
Other sources of data collection are less frequently used in health related research. *Participant observation* requires the researcher to enter a natural setting and participate in activities whilst documenting, reflecting, and informally interviewing participants. The resulting detailed and diverse data provide a differentiated insight into complex processes. *Diaries* generate temporally ordered data. They avoid retrospective re-interpretation by participants and may contain intimate information not easily elicited in interviews. However, they require participants to make a commitment to maintaining a record, e.g. of their experiences, activities, and feelings, over an extended period of time, which is often not feasible. *New media*, such as the internet, give access to a varied and rich source of data, including people’s first hand opinions in blogs and forums, newsgroups or bulletin boards. The use of such data has increased in recent years (Eysenbach 1999), but they do not usually allow direct contact with participants. Data sources like sound or images offer specific kinds of information about time, actions and events, and about the social environment that may not be captured otherwise. They require specific analysis approaches and are mainly used in social research (Willig 2008, Bauer and Gaskell 2005).

For the qualitative data collection undertaken in the context of this thesis the use of semi-structured interviews was considered most appropriate because previous research on wellbeing indicated a number of areas of interest (Schrank et al. 2013a). In addition, the goal of adapting PPT required predefined content to be included in the qualitative assessments. Semi-structured interviews allow these areas to be systematically covered while at the same time providing the flexibility to explore newly emerging themes and individual issues in detail (Bauer and Gaskell 2005).

**Data analysis**

*Coding* is the basic process on which qualitative analysis is built. Coding refers to the systematic procedure of identifying and assigning labels to specific chunks of data, e.g. text. The technique can be used in different ways to generate a structure of categories from a qualitative data set.

*Content analysis*

Content analysis is arguably the most basic of qualitative analysis methods. It identifies predefined entities of meaning, i.e. specific categories, from the data. These categories are usually designed to be mutually exclusive. Data not falling within the pre-defined content are not used in the analysis. Content analysis particularly lends itself to counting the occurrence of the specific categories in the analysed text and can
be used to later transform the data into quantitative ratings (Neuendorf 2002). Given the goal of the qualitative study presented in this chapter was to develop a dynamic framework to understand wellbeing and the processes of change involved in improving wellbeing, content analysis was not considered an appropriate method of analysis.

**Thematic analysis**

Other forms of qualitative analysis seek to identify themes and patterns across datasets which have not been pre-specified. The basic process of identifying such 'emerging' themes and patterns can be called thematic analysis. Thematic analysis has been variously regarded as a distinct technique (Braun and Clarke 2006) or as a foundational method which is applied with some variations in a number of analytic traditions (Ryan and Bernard 2000), such as grounded theory (Strauss and Corbin 1994), interpretative phenomenology (Giorgi and Giorgi 2008, Brocki and Wearden 2006), ethnography (Reeves et al. 2008) or discourse analysis (Hodges et al. 2008). In contrast to these analytic traditions, however, thematic analysis itself is not attached to a specific epistemological approach or theoretical commitment (Braun and Clarke 2006).

Thematic analysis seeks to identify, analyse and report patterns (themes) across datasets. The related process of coding can be described as either inductive or theoretical, and it can be semantic or latent.

**Inductive coding** identifies themes strongly linked to the data. They may bear little resemblance to the questions participants were asked and are not driven by the researcher's theoretical interest. Inductive analysis means coding the data without trying to fit them into a pre-existing coding frame. **Theoretical coding**, by contrast, is driven by the researcher’s theoretical or analytic interest. It may be informed by previous literature and produce a detailed analysis of a more specific aspect of the data (Braun and Clarke 2006).

Another decision in the coding process relates to the level at which themes are identified. The **semantic or explicit level** refers to the explicit surface meanings of the data and is not looking beyond what a participant said. The **latent or interpretative level** identifies underlying ideas, assumptions and concepts that are theorised to shape and inform the semantic content of the data. It has been suggested that thematic analysis will mainly focus on one of these two levels (Braun and Clarke...
However, strictly sticking to the semantic level may not allow the adequate capturing of meaning in the data, and it has been stressed that one important goal of qualitative analysis is to capture what people say regardless of the words they use for expressing themselves (Willig 2008). Also, it is often difficult to precisely determine where interpretation starts. One solution is to start the coding process at a semantic level and move on to a more interpretative level at later stages of the analysis (Braun and Clarke 2006), a method which has been applied in the present study.

Like other approaches, thematic analysis is not a linear process but a recursive or cyclical one that involves moving back and forth between the entire data set and the evolving coding frame. Also, as is generally recommended for qualitative research, writing should begin together with analysis and not come at the end of the process as it does in quantitative research. Six phases can be identified for thematic analysis (Braun and Clarke 2006). These involve:

1. Becoming familiar with the data through transcribing, repeated reading and taking notes.
2. Generating initial codes, also called open coding (Strauss and Corbin 1990), involving the identification of meaningful and interesting fragments of text and the generation of an initial list of ideas about what is in the data. This is done across the entire data set with equal attention being paid to each data item.
3. Searching for themes involves re-focusing on the analysis to search for broader more overarching themes among the initial open codes. This involves merging or splitting codes and themes and identifying levels and relationships between them.
4. Reviewing themes requires the researcher to revisit the data again to refine the themes by further splitting and collapsing them, and to identify a definition for each theme. A candidate thematic map (or coding frame) is produced with the goal to adequately capture the contours of the coded data. At the same time, this phase is used to identify any new themes that may have been missed before.
5. Defining and naming themes involves clearly describing what specific themes are and what they are not when producing a final refined coding frame which is then applied to the entire dataset.
6. The final stage involves producing the research report, which will also include information captured in notes (or memos) that have been taken throughout the analysis process.
The qualitative study reported in this chapter used thematic analysis as the most flexible and pragmatic approach to develop theory and understand participants’ individual experiences. It was supplemented with techniques taken from grounded theory to increase methodological rigour. Some background on the methodological tradition of grounded theory is provided now in order to contextualise the methodological decisions for this thesis, which are then explicitly described in Section 5.3.2.

Grounded theory

Grounded theory evolved in sociology and has the primary aim of developing contextualised theories. It is a strictly data-driven approach, i.e. it assumes that theories can emerge from data without being based on pre-existing concepts, and involves the progressive identification and integration of categories of meaning directly from data (Willig 2008). Grounded theory places great emphasis on understanding the individuals being studied and not just reporting their viewpoints. Hence, while it may start with a descriptive coding strategy it will always involve an interpretative one as well. Grounded theory is commonly considered to be a particularly thorough approach. This is reflected in the specific techniques of data collection and analysis (Lingard et al. 2008).

With regards to data collection, grounded theory may use multiple data sources for triangulation. Specific sampling strategies include theoretical sampling and sampling to theoretical saturation which both require that the sampling and analysis occur in parallel. Theoretical sampling involves collecting further data in the light of the evolving data analysis to check emerging theory against reality. Theoretical saturation means that both sampling and analysis are continued until no new categories can be identified and until new instances of variation for existing categories have ceased to emerge (Lingard et al. 2008, Schwandt 2001).

With regards to data analysis, the technique of constant comparison – repeatedly going back to the source data, re-coding and checking the evolving coding structure – has become almost synonymous with grounded theory (Strauss and Corbin 1994, Kolb 2012). Also, grounded theory utilises all available data. This means it codes all data, advisably line-by-line, and places specific importance on identifying negative cases which do not confirm the evolving theory (Schwandt 2001). Another important feature of grounded theory which further increases the rigour and depth of the analysis process is the extensive use of memos, including memos about ideas on the
evolving theory as well as self-reflective memos. It is also recommended that several researchers independently analyse all or at least parts of the data, compare the analysis at regular intervals and adapt the evolving coding frame after reaching consensus about diverging ideas (Willig 2008). At higher levels of the analysis a coding paradigm (Willig 2008) can be introduced which asks a certain question of the data. This process is also referred to as ‘axial coding’ (Strauss and Corbin 1990). However, overall the application of a coding paradigm is contested amongst grounded theory researchers (Strauss and Corbin 1994).

5.3.2. Elaboration of methods

**Interview data**

The reported study used semi-structured individual interviews with 23 service users with a diagnosis of psychosis. At the same time 14 staff members with an experience of working with people with psychosis were interviewed. All interviews contained two sections. The first set of questions asked participants about their experience of wellbeing and about strategies to improve wellbeing. The second set of questions introduced the components of standard PPT (Rashid 2008) and asked participants for their general comments on the exercises and for suggestions to adapt them for the new client group. All questions were followed up with prompts asking respondents to explain their views, give examples, and further elicit reasons and assumed mechanisms.

The topic guide (as shown in Appendix 3 for service user interviews) was slightly adapted throughout the interviews to reflect evolving issues. For example, while initially staff was asked for the experience of wellbeing in general terms, it soon became evident that participants tended to make a distinction between what wellbeing meant for themselves and what they thought it meant for service users with psychosis. Hence, the question about the experience of wellbeing was split for staff interviews into a question about staff’s own wellbeing and their own strategies to improve it, and a second question about staff ideas on service users’ wellbeing and suggested strategies for service users to improve it.

Service user data from the first set of questions on wellbeing resulted in the dynamic framework of wellbeing described in this chapter and the included published paper. Data from the second set of questions on the components of standard PPT by both service users and staff form a central part of Chapter 6.
Data analysis
Data analysis for the paper included in this chapter involved thematic analysis according to the description above supplemented with techniques from grounded theory to increase methodological rigour.

The study used the techniques of iterative inductive coding, line-by-line coding, constant comparison, identifying negative cases, the application of a coding paradigm, discussion and consensus among several researcher, and memos throughout the analysis process. This approach of supplementing thematic analysis with grounded theory techniques is in line with common practice in qualitative analysis. Today, researchers frequently do not perform a full grounded theory study but instead use a set of grounded theory techniques to enhance the rigour of their qualitative work. This “grounded theory lite” (p. 81) has itself been considered to constitute a procedure very much akin to thematic analysis (Braun and Clarke 2006).

Reflexivity
Qualitative research acknowledges both how the applied methods may have shaped the results (methodological reflexivity) as well as how the researcher as a person may have influenced the research process (personal reflexivity).

Methodological reflexivity
Methodological reflexivity addresses the validity, reliability and representativeness of the analysis.

Validity indicates the extent to which qualitative research actually describes what it aims to describe. This depends on a range of factors (Willig 2008):

(i) the specific questions asked in interviews
The two main questions asked in the semi-structured interviews with service users which served to describe the experience of wellbeing included “Can you explain to me what wellbeing means for you personally?” and “What has worked for you to support your wellbeing?” Prompt were used to stimulate further explanation. For example, the first question was rephrased to ask “What makes life worth living? What makes life good for you?” and the second question followed by “What would you advise other service users with psychosis to do in order to look after themselves and have more wellbeing/a good life?”, as soon as the narrative flow subsided. All keywords and concepts used by the participants were followed up with questions to explain them.
further, and particularly to explain how specific things made a difference for their wellbeing and why they did so.

(ii) the rapport established between the interviewer and the participants
Based on the interviewer’s (BS) self-reflection the rapport established with participants was excellent. This was facilitated by the researcher’s clinical experience with the client group, and by the strategy that interviews were started with some casual talking and participants receiving refreshments during the interview.

(iii) the social and situational context of the interview
The social and situational context of the interview was not specifically taken into account.

(iv) the method of data collection and reduction
Audio recording and verbatim transcription were used as the method of data collection leading to minimal data reduction at the stage of data collection.

(v) the analysis techniques
The analysis involved a participant validation, as described in the published paper, which adds further strength to the validity of the results.

Reliability is concerned with the question of whether the same study would have yielded the same results if conducted by different researchers. Reliability is often of less concern in qualitative research (Willig 2008). In this study reliability was enhanced by following a topic guide in the semi-structured interviews that would elicit similar information from all participants. The analysis, or at least parts of it, was carried out independently by several researchers (BS, VB, SR, JM, MS), and results were repeatedly discussed amongst researchers and adapted according to consensus in the analysis process.

Representativeness is concerned with the question of how far the study results can be generalised to the entire population in question (Willig 2008), in this case, people with a diagnosis of psychosis using specialist mental health services in the UK. Given the usually small sample sizes in qualitative studies, representativeness often is difficult to ascertain. This study used a convenience sample in that it accessed easy to reach clients only. It is therefore unclear whether the results generalise to more difficult to reach clients with psychosis, e.g. homeless people. However, the sampling strategy was purposive in that it produced a diverse sample of people with highly
variable durations of illness, current illness severity, additional diagnoses (including personality disorder and substance abuse), gender, age and ethnicity. The diagnosis of psychosis was not formally established as a research diagnosis, but instead we included people that would usually be treated in services for people with psychosis in the given context (i.e. South London). Moreover, recruitment followed the aim of theoretical saturation, i.e. was continued until additional interviews no longer led to the generation of additional categories. Overall, this suggests the sample is representative of the target population.

**Personal reflexivity**

The resulting dynamic framework of wellbeing shows significant similarity with the concept of recovery developed at the research group the researcher (BS) works in. The researcher had not familiarised herself in detail with the recovery research produced by the section before the analysis of this study had reached the discussion stage, but it is possible that she was influenced to a certain degree by the culture and knowledge surrounding her. However, the concepts of wellbeing and recovery also differ in important aspects. Having reflected on the results in detail the most likely conclusion, which is also in line with the wider published literature, may be that there is a genuine interlink between recovery and wellbeing which was not produced by a biased researcher focus.

**5.3.3 Elaboration of results**

The results of this qualitative study consolidate the findings from the systematic review by placing them in a framework applicable to individuals over time. Specifically, the layers of wellbeing factors identified in the static framework can be viewed as clusters of influences on wellbeing, which may be addressed in an intervention to improve wellbeing. Figure 5.2 shows the transformation of the static into the dynamic framework of wellbeing.
Despite the categorisation offered in both frameworks, the routes to wellbeing are complex and unique to any given individual. The clusters of influences on transition to enhanced sense of self in the dynamic framework show overlaps and are interlinked in relation to improving wellbeing. For example, non-observable internal processes such as reflection may in part depend on proximal influences such as having psychotherapy. At the same time, non-observable internal processes such as changing one’s attitude may coincide with changes in proximal factors such as the
only partially controllable aspects of relationships or living arrangements, and with observable factors such as active seeking of social interaction. All these processes may combine to produce an enhanced sense of self that manifests as an experience of improved connection.

Acceptability of PPT
In the second part of the interviews described in this chapter, participants were introduced to Positive Psychotherapy and the specific exercises it contains. They were asked about their opinion on the acceptability and suitability of PPT for service users with psychosis and for suggestions on adapting the intervention for the new client group. Overall, all participants were positive about the suitability and potential usefulness of PPT for the new client group. Suggested adaptations are outlined in Chapter 6.

5.4 Implications for the thesis
The implications of the qualitative study presented in this chapter link with the five implications identified by the systematic review in Chapter 4 (Section 4.4).

First, the systematic review identified four categories of influences on wellbeing (i.e. non-observable, observable, proximal and distal) but did not explore their potential role as targets for an intervention to improve wellbeing. The dynamic framework confirms the usefulness of the four categories for understanding and organising the components of an intervention to improve wellbeing.

Second, the systematic review did not elicit processes or include first hand experiences of people with psychosis. The dynamic framework of wellbeing serves as the basis for understanding the process of change involved in improving wellbeing in people with psychosis and for developing the intervention model to be tested in a pilot randomised controlled trial (Chapter 6 and 7).

Third, the systematic review indicated that a wide-ranging intervention addressing a broad range of wellbeing domains may be most promising for improving wellbeing. The qualitative study confirmed that many interlinked factors are important for improving wellbeing in people with psychosis. This further supports an intervention combining a range of target domains as the most promising choice.
Fourth, the systematic review did not identify an established measurement tool to measure wellbeing in people with psychosis. Understanding the process of improving wellbeing in the dynamic framework also makes the outcomes of the process explicit, i.e. the indicators of enhanced sense of self. These indicators of enhanced sense of self will inform the measurement choice for the pilot randomised controlled trial (Chapter 7).

Fifth, the systematic review identified no existing intervention to improve wellbeing in people with psychosis. This justifies the modification of an intervention used with other populations for the new client group. PPT might be a potential candidate because it simultaneously addresses a range of influences on wellbeing and shows promising results in healthy people and those with mild and common mental disorders. The interviews confirmed a positive view on PPT exercises amongst people with psychosis. In particular, the qualitative study suggests that a flexible approach incorporating individual values, preferences, and circumstances may be preferable to successfully increase wellbeing in the new client group. PPT focuses on individual strengths and positive experiences within a therapeutic framework that allows for flexibility to work on personally relevant and valued factors that may influence wellbeing rather than setting out a rigid predetermined therapy content (Section 3.2). The suitability of PPT for people with psychosis will be further explored in the qualitative analysis reported in Chapter 6, which includes the second part of the interviews. This addressed the question of how PPT should be modified to be suitable for people with psychosis.

Chapter 6 will now describe the development of an intervention to improve wellbeing for people with psychosis, i.e. the specific adaptation of PPT for this client group, the manualisation of the new intervention, and the development of a model for its effect.
Chapter 6: WELLFOCUS PPT Manual and Model

This chapter describes the development of the new intervention model and manual, based on the preceding systematic literature review (Chapter 4) and qualitative study (Chapter 5).

6.1 Introduction to model and manual development

Chapters 1 to 5 described the background relevant to this thesis, and research corresponding with the initial stages of the MRC framework for developing and testing complex interventions (Craig et al. 2008). This included the identification of relevant evidence in a systematic review and the development of relevant theory using qualitative research. Chapter 6 describes the next stage, which comprises the development of an intervention to improve wellbeing for people with psychosis, the manualisation of the new intervention, and the development of a model for its effect.

Choice of intervention

Positive Psychotherapy (PPT) was adapted for people with psychosis. There were two reasons for this choice. First, the systematic literature review (Chapter 4) established that no intervention to improve wellbeing currently exists for people with psychosis and identified PPT as a potentially promising intervention to be adapted for this client group. Second, the qualitative interviews (Chapter 5) revealed that both service users and staff were positive towards an adaptation of PPT (Section 5.3.3).

At this stage, we also chose a name for the new intervention i.e.: WELLFOCUS PPT. This name was chosen for two reasons. First, the main aim of the new intervention is to focus on wellbeing in its recipients rather than on symptoms or problems. Second, being a tool to increase wellbeing the intervention will inform recovery oriented service provision. Hence, we wanted to establish a brand link with the REFOCUS study which is hosted by the same research section at King’s College London, Institute of Psychiatry. REFOCUS is a research programme that aims to find ways of making community-based adult mental health services in England more recovery-orientated. Combining the two words, i.e. wellbeing and REFOCUS, with the name of the intervention to be adapted, i.e. PPT, resulted in the brand name for the new intervention, WELLFOCUS PPT.
6.2 Manual and model development

This stage of the project addresses Aim 2: to develop and manualise an intervention to increase wellbeing for people with psychosis. The three objectives are: 2.1 to develop an intervention (WELLFOCUS PPT) by modifying 14-session standard PPT on the basis of the theory generated from the systematic review and the dynamic framework; 2.2 to manualise the new intervention in a way suitable for use in the current project and replication elsewhere; and 2.3 to develop an explicit and testable model which identifies the mediating processes and proximal and distal outcomes arising from WELLFOCUS PPT.

6.2.1 Methods

Design
The development of the WELLFOCUS PPT comprised four stages. Stage 1 involved semi-structured interviews (Section 5.3.2) to identify candidate modifications to standard PPT and expected change processes and outcomes. Stage 2 involved an expert consultation to refine recommended modifications from Stage 1. Stage 3 involved the development of a manual and model. Stage 4 involved a stake-holder review of the WELLFOCUS PPT manual.

Participants
Participants in Stage 1 (Interviews) were service users with psychosis and mental health service staff with experience of working with people with psychosis. Service user interview data were collected in the same interviews used for the analysis described in Chapter 5. Both staff and service users were recruited from mental health services in the South London and Maudsley NHS Foundation Trust. Participants in Stage 2 (Consultation) were a convenience sample of 12 collaborators with relevant expertise, including five therapists involved in providing the intervention in the pilot RCT (Chapter 7), four health service researchers, one standard PPT specialist, and two experts in providing wellbeing interventions to the general population. Stage 3 (Manual and Model establishment) did not involve participants outside the research team. Stage 4 (Review) participants were trial therapists, service users, and service user researchers.
**Procedures**

**Stage 1: Interviews**
The topic guide for the second part of the semi-structured interviews (described in Section 5.2 and Section 5.3.2, undertaken in October and November 2011) summarised 14-session standard PPT (Rashid 2008) and its exercises (as outlined in Table 3.1). Participants were asked for feedback and suggested modification, and invited to talk about how the individual PPT exercises might affect wellbeing.

**Stage 2: Consultation**
The standard PPT manual (Rashid and Seligman, in press) and the results of the data analysis from Stage 1 were presented to experts in a one-day meeting in January 2013. Solutions to identified challenges and modifications to standard PPT exercises were proposed, and consensus was reached on adaptations to standard PPT.

**Stage 3: Manual and Model establishment**
Manualisation followed unpublished reporting guidelines called REMINDE, which identify four potential components in a manual for a complex intervention: introduction, evidence base, intervention manual, and implementation manual. The key steps when developing the WELLFOCUS manual were: developing a generic session structure, deciding on the number and content of sessions, developing guidance on therapist style, and producing session-specific hand-outs and other session tools.

Model development was undertaken in the months following the expert consultation. It involved an initial step of mapping Stage 1 and 2 results onto the dynamic framework. Based on the evidence from the systematic review (Chapter 4), the dynamic framework of wellbeing (Chapter 5) and Stages 1 and 2, key components for WELLFOCUS PPT were then identified, as were common change processes and expected outcomes of WELLFOCUS PPT.

**Stage 4: Review**
Trial therapists reviewed iterative drafts of the WELLFOCUS Manual. The pre-final manual was reviewed by the Service User Advisory Group (Biomedical Research Centre, Institute of Psychiatry) in June 2013, following which final refinements were made to the WELLFOCUS Manual.
Analysis

In Stage 1, interviews were audiotaped, transcribed verbatim, and analysed using evolving Excel tables and the qualitative data analysis software package Nvivo9. To develop the adapted intervention, a deductive coding framework of challenges and proposed modifications was initially applied. These challenges and proposed modifications were collated for both generic issues (applicable to any psychological intervention or applicable across several PPT exercises) and PPT exercise-specific issues. This resulted in four pre-specified clusters of data: generic challenges, proposed generic modifications, PPT exercise-specific challenges, and proposed exercise-specific modifications. Within each cluster, data were then inductively organised into distinct thematic areas. Where possible, correspondence between challenges and modifications was identified. The analysis was repeatedly discussed amongst the research team, comprising the PhD student, a co-research worker and the first supervisor, and adapted according to consensus. This part of the analysis produced a data set to be presented to the expert consultation at Stage 2 for external validation and the development of consensus recommendations.

In Stage 3, participants’ accounts on how the individual PPT exercises might affect wellbeing were analysed. Intervention target areas, mediating processes and expected intervention outcomes were identified in a deductive-inductive qualitative procedure. First, the WELLFOCUS PPT components (i.e. intervention exercises and homework) and information on how PPT exercises might affect wellbeing was deductively coded into the final coding frame used for the dynamic framework of wellbeing (Table 5.2). Second, the data mapped onto the dynamic framework of wellbeing were clustered in three ways: (i) WELLFOCUS PPT components into common target areas they address, (ii) envisaged mediating processes into common pathways they affect (e.g. engagement in the session on savouring leading to improved ability to mindfully enjoy things), and (iii) expected outcomes into common clusters of potential effects (e.g. positive feelings due to the improved ability to enjoy things). The clustering was repeatedly discussed with the research team and subsequently refined and reorganised until consensus was reached that target areas, processes and outcomes had been satisfactorily captured by the model.
6.2.2 Results

**Stage 1: Interviews**

A total of 23 service users with psychosis (Table 5.1) and 14 staff members (mean age: 36.5 years, s.d. 10.3; 71% female; mean length of relevant experience 11.6 years, s.d. 12.4) were interviewed.

Four generic themes emerged as challenges: *Attitudes, Illness, Engagement* and *Interaction*. Corresponding ideas for changes and solutions for challenges were proposed.

**Attitudes:** Participants were concerned that the positive approach may be rejected by the recipients of WELLFOCUS PPT. Recipients may also have unrealistic positive or negative expectations, and a fear of failure. Proposed corresponding modifications included an emphasis on being realistic, expecting negative feelings, and discussing expectations and limitations.

**Illness:** Participants felt that concentration and motivation difficulties may interfere with PPT exercises. Also, people with severe mental illness may have experienced challenging or traumatic life events which may come up during therapy and hinder a focus on positive experiences or solutions. Proposed modifications included an emphasis on using clear, understandable language; avoiding theory, abstraction and didactic style; emphasising organisation and structure but allowing flexibility; reflecting on difficulties and adapting tasks according to individual needs; and using small concrete steps when planning activities. In order to avoid triggering traumatic memories, exercises dealing with past experiences may start with asking for small and recent examples.

**Engagement:** Identified reasons for lack of engagement with session tasks or homework included that exercises may feel meaningless, contrived or superficial, concepts may be too abstract, there may be negative connotations with homework, or a lack of social or financial opportunities. Proposed modifications to increase engagement included an emphasis on clearly explaining the overall rationale and providing a session-by-session outline; focusing on aspects of an individually meaningful life and personal values; identifying realistic, personal goals; starting with small tasks and gradually introducing and increasing more challenging tasks; providing personalised feedback and support; planning exercises in sessions; and awareness of the negative connotation of homework. Further suggested strategies
included reminder calls or texts, awarding certificates, having afternoon rather than morning sessions, breaks with refreshments, and providing information to take away.

**Interaction:** Interviewees were concerned about problems related to social contact in therapy groups, including e.g. anxiety relating to self-disclosure, lack of self-confidence, unfavourable self-comparison, difficult interaction with dominant group members, or lack of interest in other people. Proposed modifications to address these issues included an emphasis on using warm-up exercises; fostering mutual acceptance and stressing equality in group discussions; creating a trusting environment; promoting the display of honest interest in others; and therapist self-disclosure as well as the use of humour to normalise experiences and integrate the group.

The analysis also identified PPT exercise-specific challenges and proposed solutions. Participants felt that two sessions from standard PPT – Satisficing vs. Maximising (session 8) and Altruism (session 13) – might be especially challenging to understand, not meaningful, or even appear patronising for severely ill people with psychosis. Removal of these sessions from WELLFOCUS PPT was suggested at this stage. Identified issues and proposed solutions for all other sessions are outlined in Table 6.1.
Table 6.1: Service user and staff views on exercises from standard PPT

<table>
<thead>
<tr>
<th>Standard PPT session</th>
<th>Challenges</th>
<th>Proposed Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Orientation</td>
<td>No specific challenges</td>
<td>No specific modifications proposed</td>
</tr>
<tr>
<td>2. Character Strengths</td>
<td>Difficulties identifying strengths; strengths may be disputed; others may abuse one’s strengths; strengths discussion is embarrassing; VIA questionnaire is too long</td>
<td>Empower/assist recipients: everyone has strengths; everyone is valued; encourage group support for identifying strengths (“other people can often see strengths that we can’t”) ‘Three Good Things’ should be a separate session, emphasis on small good things, recording at flexible times, allow alternatives for writing (e.g. drawing, painting, collecting keepsakes), normalise experience of no good things on some days.</td>
</tr>
<tr>
<td></td>
<td>For the homework, i.e. Blessing Journal, identification of three good things every night is too much, literacy issues, too formulaic or repetitive, difficult to remember as a daily task</td>
<td>‘Three Good Things’ should be a separate session, emphasis on small good things, recording at flexible times, allow alternatives for writing (e.g. drawing, painting, collecting keepsakes), normalise experience of no good things on some days.</td>
</tr>
<tr>
<td>3. Signature Strengths</td>
<td>Difficulties identifying activities; unrealistic ideas; anxiety about lack of skills, abilities, or performance; unachieved goals may lead to negative feelings (“feeling like a failure”)</td>
<td>Focus on realistic goals; have alternative, back-up goals; encourage teaching of strengths to others (including therapists); discuss strengths with others outside the therapy; in-session planning, follow up and recording of achievements</td>
</tr>
<tr>
<td>4. Good vs. Bad Memories</td>
<td>Difficulties identifying good memories; focus on bad memories unhappy childhood a, trauma) and distress may accentuate negative appraisal; memory problems; belief that good memories are not deserved</td>
<td>Establish values and goals to stimulate memories; focus on recent memories; normalise positive and negative memories; emphasise self-kindness, help notice positive feelings (“good memories make you smile”)</td>
</tr>
<tr>
<td>5. Forgiveness</td>
<td>May “unlock” anger, trauma, shame, and depression; feeling vulnerable or disempowered (“an invitation to be harmed again”); not ready to forgive; some events are ‘unforgivable’; different understandings of concept; difficult to achieve in short intervention</td>
<td>Avoid talking about trauma, construe as feeling “let down by someone”; acknowledge forgiveness is a personal process that takes time; consider reasons for forgiveness; begin with small examples; therapist self-disclosure; emphasise connotations like “lifting a burden”, “making peace”, “putting anger and bitterness behind you”, “moving on”, becoming a “better, stronger person”; be realistic: not all need be forgiven, those you forgive need not stay friends; consider forgiving oneself instead of/in addition to others.</td>
</tr>
<tr>
<td>Section</td>
<td>Challenges</td>
<td>Solutions</td>
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<td>---------------------------------</td>
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<tr>
<td>6. Gratitude</td>
<td>Difficulties identifying people or events; increased awareness of lack of positives; triggers negative thoughts or envy; disproportionate gratitude: overly grateful for small things may be disempowering (“I'm always the one who is helped”); distribution of gratitude letter may be inappropriate; literacy difficulties; uncommon to express gratitude in some cultures</td>
<td>Discuss people who deserve recognition; discuss appropriate level of gratitude; contextualise gratitude: emphasise reciprocal (“give and take”) interactions; warm-up exercise to build up to writing a letter; discuss feelings of letter recipients, who should see letter, appropriate time to send; alternatives to letter, e.g. greeting card, making something, verbal thanks, writing letter to oneself</td>
</tr>
<tr>
<td>7. Feedback</td>
<td>No specific challenges</td>
<td>No specific modifications proposed</td>
</tr>
<tr>
<td>9. Hope, Optimism &amp; Posttraumatic Growth</td>
<td>Content may be distressing; evoke negative memories, disappointments, embarrassments, or serious ongoing problems (e.g. abuse, bereavement, harmful relationships); not everything has a positive side; might feel patronising, belittling experience, denying the problem, superficially positive</td>
<td>Avoid reactivating trauma: focus on recent “disappointments”, frame as &quot;learning from your mistakes”; begin with small examples; be realistic: some events might have little positive outcome; normalise negativity in experience; consider lessons learned and how to implement them in the future</td>
</tr>
<tr>
<td>10. Positive Communication</td>
<td>Avoidance or fear of social situations; feel unconnected to people or groups; feeling inferior; difficult to transfer to real life situations; psychotic misinterpretation of interpersonal communication, e.g. suspicion; takes too long to learn</td>
<td>Discuss valuing relationships and social interactions; discuss concerns over social settings; normalise social anxiety and negative experiences; use group to practice; therapist acts as role model; encourage small, meaningful interactions.</td>
</tr>
<tr>
<td>11. Signature Strengths of Others</td>
<td>Difficulty finding meaningful tasks or others to collaborate with; no family or difficult family relationships, feel uncomfortable socialising; difficult to meet up with group members outside group; bored by long activities.</td>
<td>Let group relationships and activities develop naturally; role-play in pairs; encourage small, accessible tasks; balance and alternate group pairings, encourage family participation but normalising relationship difficulties, identifying mediator to discuss family problems, nominate several possible family members or friends for involvement</td>
</tr>
<tr>
<td>12. Savouring</td>
<td>Difficulty feeling positive emotions or “letting go”; not valuing anything; frightened of good feelings; enjoyment “cannot be learned”, everyone enjoys things differently; “pleasure” suggests superficial fun: may be harmful, e.g. substance abuse; food sensitivity, weight issues, eating disorders.</td>
<td>Discuss and normalise enjoyment and values; let participants experiment; emphasis small pleasurable things (e.g. cup of tea, crossword); be conscious of participants with weight issues or eating disorders and pleasurable but harmful activities: avoid word “pleasure”.</td>
</tr>
<tr>
<td>14. The Full Life</td>
<td>No specific challenges</td>
<td>No specific modifications proposed</td>
</tr>
</tbody>
</table>
Based on the analysis, PPT exercises were organised into three clusters that correspond to how challenging the exercises were expected to be for people with psychosis. This was the first step towards sequencing WELLFOCUS PPT sessions. Cluster 1 included the easier exercises, comprising Savouring and Three Good Things. Cluster 2 included sessions of intermediate difficulty, comprising Character Strengths, Signature Strengths, Signature Strengths of Others, and Positive Communication. Cluster 3 included sessions perceived as most challenging, comprising Good vs. Bad Memories, Gratitude, Forgiveness, and Hope, Optimism & Posttraumatic Growth.

**Stage 2: Consultation**

The expert consultation discussed all elements of the Stage 1 analysis and produced general recommendations for WELLFOCUS PPT and specific recommendations for adaptations to PPT session contents. The original 14 sessions of standard PPT were adapted into 11 sessions of WELLFOCUS PPT. The principle decision was made to structure WELLFOCUS PPT as a group intervention as this will allow additional gains through social interaction for recipients. This is specifically relevant since social relationships and connectedness were identified as important for improved wellbeing (Section 5.2).

The four general Stage 1 themes of **Attitudes**, **Illness**, **Engagement** and **Interaction** were used to guide general recommendations. The Stage 1 analysis on exercise-specific challenges and proposed solutions (Table 6.2) was used to guide the formation of exercise-specific recommendations. Where appropriate, Stage 1 suggestions that did not directly lead to adaptations of session content were included in the intervention manual as therapist tips.

**General adaptations**

General adaptations included the modification of session and exercise titles to increase clarity and accommodate psychosis-specific challenges, such as potentially impaired skills in abstract reasoning.

Some standard PPT homework exercises were perceived as insufficiently connected with session content. Continuity was improved by adapting and rearranging homework tasks for individual sessions, the sequence of sessions, and by including a recap of previous content at the beginning of each session. In terms of sequencing, the three clusters of PPT sessions established in the Stage 1 were approved. However, the
experts emphasised that sessions should culminate in predominantly positive themes, hence, introducing a celebration at the end.

Homework was agreed to be important but challenging. It was relabelled as Ongoing Exercise and integrated with the main session exercises. Ongoing Exercises should begin in each session, with planning and encouragement to continue them at home. Ongoing Exercises would be incentivised with gifts (e.g. Good Things Boxes) and between-session phone call reminders.

WELLFOCUS PPT exercises would be supported with clear, concise worksheets in lay language, with colourful illustrations, and reducing some of the complex content from standard PPT. Writing exercises were deemed important and retained, but literacy was de-emphasised by including alternative options, such as drawing.

The experts agreed that all WELLFOCUS PPT exercises should be personal, experiential, and interactive. Therapists should help participants to choose goals for exercises that are specific, attainable, and personally meaningful. In particular, a distinctive feature of WELLFOCUS PPT should be the importance of valuing small things. Meaningfulness and personal values should be conveyed at every level, including facilitating the development of a meaningful positive self-narrative for each recipient, therapist self-disclosure, therapist involvement in exercises, as well as appropriate choices of refreshments, venue and music. The standard PPT principle of identifying and using positives to address or cope with negatives was incorporated into the WELLFOCUS PPT manual and extended to counteract psychosis-specific challenges, e.g. paranoid ideas.

**Specific session adaptations**

Major changes to session content for WELLFOCUS PPT in comparison to standard PPT are summarised in Table 6.2.
### Table 6.2: WELLFOCUS PPT adaptations to session content

<table>
<thead>
<tr>
<th>Standard PPT session</th>
<th>Adaptation in WELLFOCUS PPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Orientation to PPT</td>
<td>The session was relabelled as ‘Welcome to WELLFOCUS PPT’</td>
</tr>
<tr>
<td>2. Character strengths</td>
<td>Both strengths sessions were included but renamed into ‘Identifying a Personal Strength’ and ‘Using Personal Strengths’, with an emphasis on small and achievable short-term goals in the related exercises and extensive feedback at the following session</td>
</tr>
<tr>
<td>3. Signature Strengths</td>
<td>The Values in Action Inventory of Strengths from standard PPT was replaced by laminated A4 pictures representing character strengths for discussion</td>
</tr>
<tr>
<td></td>
<td>The five character strengths identified in standard PPT were reduced to a single personal strength.</td>
</tr>
<tr>
<td></td>
<td>The Session 2 homework ‘Three Good Things’ was introduced as a separate session and renamed to ‘Good Things’ to reduce the potential burden of identifying several things. Colourful Good Things Boxes were introduced to allow flexibility when collecting good things and reduce the focus on literacy.</td>
</tr>
<tr>
<td>4. Good vs. Bad Memories</td>
<td>The session was removed. Some content was integrated into the sessions on Gratitude, One Door Closes Another Door Opens and Forgiveness.</td>
</tr>
<tr>
<td>5. Forgiveness</td>
<td>The session was split into two sessions due to the perceived challenges of the topic. Concerns that participants may not understand forgiveness were addressed with explanatory hand outs. Forgiveness exercises should be conceptualised as thinking about recent and preferably small examples.</td>
</tr>
<tr>
<td>6. Gratitude</td>
<td>The session was retained but positioned at a later point in the sequence of sessions in WELLFOCUS PPT. Sending the letter is not encouraged.</td>
</tr>
<tr>
<td>7. Mid Therapy Check</td>
<td>The session was removed to shorten the overall duration of the intervention and thereby increase its acceptability.</td>
</tr>
<tr>
<td>8. Satisficing vs. Maximising</td>
<td>The session was removed. Where appropriate, content was included in the strengths sessions.</td>
</tr>
<tr>
<td>9. Hope, Optimism &amp; Posttraumatic Growth</td>
<td>The session was relabelled as its standard PPT homework title, ‘One Door Closes Another Door Opens’.</td>
</tr>
<tr>
<td>10. Positive Communication</td>
<td>The session title and its homework ‘Active Constructive Responding’ (i.e. responding positively to other people) were combined into ‘Positive Responding’, to be more self-explanatory, and modified by instructing therapists to model positive responding. This eliminated it as a formal session but preserved it as a communication exercise in several sessions.</td>
</tr>
</tbody>
</table>
Stage 3: Manual and Model establishment

Manualisation

A draft WELLFOCUS Manual was produced including generic advice for therapists and specific session contents. WELLFOCUS PPT is delivered by two therapists who follow the WELLFOCUS Manual. Effective therapist self-disclosure (Barnett 2011) is encouraged and prompted in all sessions. Therapists participate in the exercises themselves. Recipients are not prohibited from sharing distressing, unpleasant, or negative states and experiences. Instead, any ‘negative’ accounts are validated with therapists establishing a link to one or more target areas of the WELLFOCUS Model (as outlined in the next section). WELLFOCUS PPT is provided regardless of current symptom severity. However, it is suggested to offer WELLFOCUS PPT only to those who are cognitively able to follow the content, as determined by the relevant clinician.

WELLFOCUS PPT sessions follow a generic structure: 90 minutes sessions, with 5 minutes savouring of music at the beginning and end, and a 10 minute mid-session break with refreshments. To emphasise continuity, each session begins with a welcome, recap and warm-up exercise. Thereafter the main session topic and Ongoing Exercise are introduced, which recipients are encouraged to continue and reflect on at home. The overall emphasis of standard PPT is shifted towards more experiential tasks instead of theory to stimulate participant engagement and facilitate concentration.

The WELLFOCUS PPT Manual contains session-by-session guidance, example scripts, and therapist tips for all 11 sessions. WELLFOCUS PPT uses additional

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11. Signature Strengths of Others
   The session was grouped together with earlier strengths session and renamed to “Using Strengths Together”. The family involvement component was minimised and broadened to include friends or clinicians, especially for those with few friends or family.

12. Savouring
   The session was positioned earlier in the course of the therapy. A range of different eating and drinking choices is provided to practice savouring.

13. Altruism
   The session was removed. Where appropriate, content was included in the strengths sessions.

14. The Full Life
   The session was modified into a celebration. Through recapping and reprising, the celebration retains the integrative elements of the session ‘The Full Life’ but places greater emphasis on accomplishment.
supporting materials, including the WELLFOCUS Journal, session hand-outs, strengths pictures, Good Things Boxes, and WELLFOCUS PPT music. Participants receive the WELLFOCUS Journal in the first session and are encouraged to personalise, bring and use it in every subsequent session. The journal includes summary pages for all sessions giving a rationale and describing the Ongoing Exercise in accessible language and with colour-coding. Additional handouts and work sheets which fasten in the WELLFOCUS Journal are distributed in each session. WELLFOCUS PPT music for the savouring exercise at the beginning and end of each session was selected in collaboration with musicians. The 11 tracks are all instrumental and chosen to correspond in pitch, pace and ambience to session topics.

**Model development**
An intervention model outlines the hypothesised processes and outcomes. It guides design choices for the evaluation of the intervention. The MRC recommends the inclusion of an intervention model at an early stage of the research process and acknowledges that more than one study may be required to progressively refine the model before the definitive evaluation of a complex intervention (Craig et al. 2008). The development of the theory-based model for WELLFOCUS PPT is now described.

The process of model development involved a mapping of components of WELLFOCUS PPT on to the dynamic framework of wellbeing, as shown in Figure 6.1. Components addressed by WELLFOCUS PPT and outcomes expected are highlighted in bold in the figure.

Some categories are directly and explicitly addressed, e.g. personal strengths, others are indirectly addressed, e.g. likely to be positively impacted on by other components, or up to participants to be picked for an exercise. For example, mental health status may be positively affected by improved coping through developing personal strengths. Spiritual practice may be picked as a personal focus in planned activities or brought up by participants in the forgiveness sessions but is not explicitly included as an exercise in the intervention.
Dynamic framework category 1: Determinants

Personality determinants are explicitly addressed. WELLFOCUS PPT focuses on personality issues by identifying and fostering participants’ strengths and by helping them to articulate personal values and interests. All activities planned and carried out during the intervention are built on the individual’s strengths, values and interests.

Memories are also explicitly addressed. WELLFOCUS PPT uses both positive and negative memories to identify strengths and increase positive emotions (e.g. in the intervention component ‘Positive Introduction’, and ‘One Door Closes, Another Door Opens’) and to foster positive relations with others (e.g. in the intervention components ‘Gratitude’ and ‘Forgiveness’).

Health status is not explicitly addressed. However, in line with the assumptions for standard PPT (Rashid 2008), mental health status, especially depressive symptoms and coping, are expected to improve due to the focus on positive experiences and strengths.
**Dynamic framework category 2: Influences**

Non-observable influences: Attitudes are addressed in that participants’ thinking style, their expectations, and their mode of social comparison are expected to shift towards the positive as a result of all intervention components. Positive future thinking is fostered in that personally positive goals are set and followed especially in the components ‘Using Personal Strength’ and ‘Using Strengths Together’. Reflection and adaptive cognitive processes are stimulated by all intervention components. For example, the component ‘Savouring’ helps to value and appreciate small things, the component ‘One Door Closes, Another Door Opens’ helps to embrace limitations, the component ‘Forgiveness’ directly targets forgiveness, the component ‘Good Things’ helps to shift attention towards the positive. Reflection within the group on all tasks throughout the intervention helps to gain insight, change perspective, and take a more positive stance. Reflection on the action goals (e.g. in ‘Using Personal Strength’) particularly supports finding solutions and solve problems.

Observable influences: Social interaction is addressed by fostering social skills and facilitating connection in components such as ‘Using Strengths Together’ and ‘Positive Responding’. Mutual support and positive feedback is encouraged throughout but specifically targeted in the components ‘Positive Introduction’, ‘Using Strengths Together’, ‘Positive Responding’, and ‘Celebration’. Having a treat is encouraged in the component ‘Savouring’ which fosters participants’ ability to enjoy and savour things and moments. Kindness is addressed throughout the therapy, but specifically focused on in the components ‘Using Strengths Together’, ‘Forgiveness’, and above all ‘Gratitude’ which facilitates the experience of giving something back to others. Engaging in activities is encouraged throughout the therapy in the weekly ongoing tasks.

Self-care is not a direct target of the intervention, but can be picked as a goal, e.g. for ‘Using Personal Strength’, and is possibly fostered through ‘Savouring’. A focus on spiritual practice is not explicitly included since spirituality may be a controversial issue for some participants, especially given their expected wide range of cultural backgrounds. However, it is up to the individual to include spiritual practise or attending faith communities in the context of components such as ‘Using Personal Strength’, ‘Using Strengths Together’, ‘Good Things’, ‘Forgiveness’ or ‘Gratefulness’.

Proximal influences: Relationships within and outside the group are an important focus throughout the intervention. Relationships are explicitly dealt with in the
intervention components ‘Positive Responding’, ‘Using Strengths Together’ and also ‘Forgiveness’. Psychotherapy is addressed by the fact that participants engage in WELLFOCUS PPT as a form of psychotherapy.

Basic needs and issues around antipsychotic medication or mental health services and staff are not a target of WELLFOCUS PPT. Targeting these areas requires different interventions involving more far reaching action, including e.g. support with benefits or housing issues, or the involvement of other mental health professionals.

Distal influences: No distal influences are targeted by WELLFOCUS PPT. A focus on societal values, the environment or the economy would require a different approach, on a societal rather than individual level. Such interventions may include activities to reduce stigma, access to green spaces, or employment programmes for people with mental health problems, since self-stigma (Tang and Wu 2012), green spaces (Bowler et al. 2010, Lee and Maheswaran 2011), and unemployment (Lucas et al. 2004, Evans and Repper 2000) have all been linked to wellbeing.

Dynamic framework category 3: Indicators

The expected outcomes of the intervention elicited in the qualitative interviews mapped very well onto the signifiers of wellbeing. Service user and staff interviews suggested that all of the indicators of enhanced sense of self, i.e. good feelings, symptom relief, attachment, hope, self-worth, empowerment, and meaning, may be positively affected by WELLFOCUS PPT.

The WELLFOCUS Model

The WELLFOCUS Model describes (i) the target areas of the intervention, (ii) the hypothesised intermediate processes leading to outcome, and (iii) the proximal and distal outcome domains expected to be improved by WELLFOCUS PPT. The WELLFOCUS Model is shown in Figure 6.2.
**Intervention**

The exercises contained in WELLFOCUS PPT map onto four areas of activity (or target areas) i.e.: increasing positive experience, amplifying strengths, fostering positive relationships, and creating a more meaningful self-narrative. Table 6.3 displays the components of WELLFOCUS PPT and specifies the target areas they address.
<table>
<thead>
<tr>
<th>Session</th>
<th>Ongoing Exercise</th>
<th>Content and additional information</th>
<th>Target area(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Welcome to WELLFOCUS PPT</td>
<td>Positive Introduction</td>
<td>Group guidelines, rationale, positive responding</td>
<td>Positive experiences Amplifying strengths</td>
</tr>
<tr>
<td>2. Savouring</td>
<td>Planned savouring activity</td>
<td>Mindful eating, drinking and listening exercises</td>
<td>Positive experiences</td>
</tr>
<tr>
<td>3. Good Things</td>
<td>Identify good things</td>
<td>Identify recent good things using the Good Things Box</td>
<td>Positive experiences</td>
</tr>
<tr>
<td>4. Identifying a Personal Strength</td>
<td>Identify a character strength</td>
<td>Identify one character strength using strengths pictures</td>
<td>Amplifying strengths</td>
</tr>
<tr>
<td>5. Using Personal Strengths</td>
<td>Strength Activity</td>
<td>Plan and carry out an activity using your strength</td>
<td>Amplifying strengths</td>
</tr>
<tr>
<td>6. Using Strengths Together</td>
<td>Strength Activity with Significant Other</td>
<td>Plan and carry out activity that uses both people’s strengths</td>
<td>Amplifying strengths Positive relationships</td>
</tr>
<tr>
<td>7. Forgiveness 1</td>
<td>A Sea of Forgiveness</td>
<td>Focus on letting go of a grudge</td>
<td>Positive relationships Meaningful self-narrative</td>
</tr>
<tr>
<td>8. Forgiveness 2</td>
<td>Forgiveness letter</td>
<td>Identify a person to forgive and write them a letter</td>
<td>Positive relationships Meaningful self-narrative</td>
</tr>
<tr>
<td>9. One Door Closes Another Door Opens</td>
<td>One Door Closes Another Door Opens</td>
<td>Identify positive conclusions from negative experiences</td>
<td>Meaningful self-narrative</td>
</tr>
<tr>
<td>10. Gratitude</td>
<td>Writing a gratitude letter</td>
<td>Identifying a person you have never properly thanked and write them a letter</td>
<td>Positive relationships</td>
</tr>
<tr>
<td>11. Celebration</td>
<td>Positive responding</td>
<td>Celebrate achievements</td>
<td>Positive experiences</td>
</tr>
</tbody>
</table>

It was decided to summarise exercises in target areas, or common goals, to represent the intervention in the model. We explicitly decided not to refer to “active ingredients” or “specific components” for two reasons. First, the specific ingredients described for psychological therapies in the literature are highly diverse, their definitions mostly vague, and the distinction between specific and non-specific ingredients difficult. For example, for cognitive behavioural interventions “maximizing mood-elevating activities”, “activity scheduling” (Lund and Lund 2013), “establishing a consistent sleep pattern”, or “identifying and challenging unhelpful illness beliefs” have been described as active ingredients (Lewis-Beck et al. 2003), while for counselling “unconditional positive regard” or “therapeutic relationship” were considered active ingredients (Lewis-Beck et al. 2003). Second, the delivery of active ingredients differs across therapists and time even in highly standardised studies (Lund and Lund 2013) adding to the importance of non-specific ingredients for treatment effect. Common therapy
factors have even been suggested to be potentially more effective than specific ingredients (Messer and Wampold 2002).

Processes
The processes described by interviewees as potentially triggered by WELLFOCUS PPT closely reflected the processes in the dynamic framework. Since the aim was to develop a testable model of the processes involved in WELLFOCUS PPT, the complexity of the data had to be greatly reduced for model development. Attendance and engagement in the sessions and Ongoing Exercises along with the subjective perception of their benefit were identified as the common necessary requirements to trigger individual change processes. Hence the WELLFOCUS Model was built on these basic measurable components, rather than specifying more precise causal chains of reactions for which quantitative measurement might be unfeasible.

For example, session five and the related ongoing task, i.e. identifying and practising a personal strength, may involve very different processes for different participants. Taking the specific strength ‘appreciation of beauty’ as an example, this may involve for one person going for a walk in the park, leading to physical exercise, reflection and relaxation while enjoying nature, and further to a better bodily feeling, a feeling of serenity, and better symptom coping. For another person the same strength may be displayed by playing music together with another person leading to improved connection, feelings of joy and better self-worth. In order for such complex processes to be triggered by WELLFOCUS PPT, participants have to engage in the session exercise (i.e. identify a strength), find the exercise beneficial (i.e. take on board what they have learned in the session), be prepared to do the Ongoing Exercise (i.e. have the benefit of anticipation and intent), actually do the Ongoing Exercise (e.g. take a walk in the park) and find it beneficial (i.e. experience the related individual processes and embrace the experience).

Outcomes
The outcome areas could not be condensed any further in comparison with the dynamic framework of wellbeing without losing relevant information. Hence, all indicators of wellbeing from the dynamic framework were included as proximal outcomes of the intervention in the WELLFOCUS model. The understanding of wellbeing identified in Chapter 5 - enhanced sense of self - was the distal outcome.
**Stage 4: Review**

WELLFOCUS PPT therapists reviewed the draft manual and suggested minor modifications. One of the experts, who had experience providing wellbeing interventions to the general population, reviewed the hand-outs.

Six members of the Service User Advisory Group reviewed the draft manual. They were not prompted with respect to the four generic themes that had emerged from Stage 1, but identified four key similar issues: *Attitudes, Illness, Behaviour change,* and *Confidentiality.* They also suggested further modifications.

*Attitudes:* They suggested that the positive approach could appear inauthentic and patronising (i.e. “it can be hard to see or hear that there might be light at the end of the tunnel”). WELLFOCUS PPT was modified so that therapists place particular emphasis on being genuine and realistic.

*Illness:* They emphasised that problems and symptoms should be acknowledged where necessary. WELLFOCUS PPT was modified so that therapists emphasise that they are not ignoring the negatives when group members discussed problems.

*Behaviour change:* They emphasised that the tendency to relapse in psychosis must be acknowledged (“benefits may last only as long as the therapy”). WELLFOCUS PPT was modified so that Ongoing Exercises encourage behaviour change, recaps would encourage continuation of all exercises, the Celebration session emphasises continuation in addition to achievements, and the WELLFOCUS Journal includes all materials for continuation and is given to group members to keep.

*Confidentiality:* They urged that confidentiality should be strictly adhered to in a group setting. WELLFOCUS PPT was modified so that confidentiality is highlighted in the WELLFOCUS PPT manual for Session 1.

Following the revisions resulting from the stakeholder review, the WELLFOCUS Manual was finalised.

**6.3.3 Discussion**

The research described in this chapter reflects three achievements important for this thesis. First, the acceptability of PPT for people with psychosis and its likely suitability to increase wellbeing in this client group was established and a decision made to progress the adaptation. Second, standard PPT was adapted into WELLFOCUS PPT
and manualised. Third, the WELLFOCUS Model was developed. The new complex intervention and model will be tested in a pilot RCT with nested comprehensive process evaluation, as described in Chapter 7.

**Strengths and Limitations**

Standard PPT is already being modified for clinical populations other than people with depression, for example smoking cessation (Kahler et al., 2013) and brain injury rehabilitation (Evans, 2011). The importance of a positive identity for mental health recovery (Leamy et al., 2011) indicates the relevance of PPT to psychosis. The one previous modification of standard PPT for psychosis (Meyer et al., 2012) was based on 6-session standard PPT. It has been tested with service users with psychosis in an uncontrolled study which recruited from a single specialist psychotherapy service, and thus limits generalizability (Zwarenstein et al., 2008). These design limitations were addressed in the present study. WELLFOCUS PPT is based on an established scientific framework (Craig et al., 2008). It employs an evidence-based theoretical framework of a systematic review and qualitative work specific to the clinical population to understand the processes involved, modifies the larger 14-session PPT intervention (Rashid & Seligman, 2013), is based on an explicit and testable model, and was developed in a diverse ethnic and cultural context. It will be evaluated in a range of community mental health services, with a control group and a larger sample size in a pilot RCT.

Modifications from standard PPT to WELLFOCUS PPT were based on Stages 1-4 (qualitative study, expert consultation, manualisation, stake-holder review). It was found that Stage 4 themes overlapped with Stage 1 themes, lending further triangulation support to the theory base. In addition, Stage 4 broadened the scope of modifications for WELLFOCUS PPT by including distal concerns, with themes of behaviour change and confidentiality. Important ethical concerns, such as confidentiality, and longer-term issues, such as relapse and continuation were emphasised. The latter concern suggests that, for service users, it is important to recognise the importance within any psychotherapeutic intervention of supporting the use of learned skills beyond the clinic, which has been recommended and recognised as a challenge in treatment provision (Bellg et al., 2004).

Limitations include the fact that the data acquisition for theory development (i.e. the dynamic framework) and intervention model development occurred in a single interview. This may partly explain the excellent fit of the intervention model when
mapped onto the dynamic framework. A further limitation may be the convenience sample of experts for the consultation (Stage 2) and the fact that a broader number and range of experts could have been consulted.

Despite the fact that continuation and transfer of skills into daily life emerged as significant factors, the Mid-Therapy Feedback Session was eliminated and replaced by previous session recaps at the beginning of each session. The rationale for this decision was to reduce the overall duration of the therapy, which was perceived as potentially off-putting and challenging for people with motivation problems. The pilot RCT will establish if more time needs to be devoted to repetition and continuation in WELLFOCUS PPT for psychosis.

Implications for the thesis
The WELLFOCUS Model and Manual allow the adapted intervention to be tested in an RCT. The methods for the pilot RCT conducted in the context of this thesis are described in Chapter 7. The WELLFOCUS Model also informed the choice of process and outcome measures, as described in detail in Chapter 7.
Chapter 7: Methods

The next stage in the development of WELLFOCUS PPT is evaluation in a pilot RCT, followed by refinement. This chapter describes the methods for the pilot RCT.

7.1 Introduction to WELLFOCUS PPT evaluation methods

Three key decisions informed the design of the evaluation. First, the decision to use a randomised controlled trial (RCT) design. Second, the need for the RCT to establish feasibility i.e. rigorously examine the potential usefulness and acceptability of the intervention and estimate relevant parameters for the evaluation strategy, in order to inform a later definitive RCT. Third, we wished to use a pragmatic approach to trial design with a specific emphasis on processes, to ensure external validity whilst also ensuring adequate internal validity (Dunn 2013). This approach will maximise real-world applicability of the findings, by allowing a direct translation of the outcomes to routine settings whilst also explaining processes occurring during WELLFOCUS PPT. Therefore, a nested process evaluation was conducted to elicit how the intervention works, including potential mediators and moderators of effectiveness, and to aid interpretation of the outcomes of the RCT (Lewin et al. 2009).

Randomised controlled trials

In general, RCTs are used to assess the benefits and harms of interventions in health care. They are considered to be the gold standard for clinical trials, creating the most robust results. If rigorously designed and implemented they allow inferences about the causal effects of an intervention. The MRC framework recommends RCTs at an early stage in the research process for developing and testing complex interventions (Craig et al. 2013). Alternative initial evaluation designs such as uncontrolled intervention studies, or non-randomised controlled studies, would not allow establishment of critical parameters for a definitive evaluation, such as the feasibility of the intervention and the processes involved in testing it, or the calculation of a sample size.

Three features of RCTs are known to impact on the quality of their results: randomisation, blinding, and the choice of control group (Moher 1999, Juni 2001, Hart et al. 2007). It has been suggested that over 50% of studies fail to adequately address these major sources of bias. This significantly and unnecessarily decreases their usefulness both to inform further research as well as to benefit clinicians and patients (Chalmers and Glasziou 2009).
Randomisation, if undertaken independently, minimises the risk of selection bias. Provided numbers are large enough, randomisation also means that non-specific variables are likely to be equally balanced between groups reducing the likelihood of confounding. This would not be the case in non-randomised controlled trials. Randomisation also guarantees the validity of subsequent statistical tests of significance (Dunn 2013).

Blinding can occur on four levels: the research participant, the care provider, the assessor, and the statistician. Blinding participants and care providers prevents performance bias, i.e. the preferential receipt of additional treatment in one group, as well as differences in placebo response between groups. Blinding assessors adds the benefit that independent judgements can be made about the outcome, preventing detection bias (Juni et al. 2001). In trials investigating psychotherapeutic interventions it is usually impossible to blind the participants and the therapists as to which intervention they receive or deliver (Freedland et al. 2011). Substantial financial, personnel, and organisational input is needed to blind assessors in trials of psychological interventions, yet blinding is often difficult to maintain in practice, e.g. due to participants disclosing their allocation on assessment.

RCTs always investigate an intervention relative to a control condition. Together with randomisation the use of a control condition ensures the trial’s internal validity. At the same time control conditions may also threaten internal validity, for example by influencing outcome expectancies or changing health-promoting behaviour (Mohr et al. 2009). The choice of control group in an RCT is also dependent on the aims of the trial and will influence the type of evidence that can be created, e.g. the establishment of specific active ingredients, the critical dose of an intervention, or superiority of one intervention over another (Stice et al. 2007). The choice also heavily impacts on the personnel and financial resources of a trial. Hence, the choice of control condition has to be carefully considered.

The WELLFOCUS Trial used an independent randomisation procedure, it is non-blinded, and it used a Usual Care control condition. The relatively small cost of introducing an independent randomisation procedure was deemed proportionate, since inadequate concealment is a known source of bias and randomisation a low-cost approach to improving the internal validity of the trial, i.e. the extent to which the outcomes can be attributed to the experimental intervention and not to an alternative explanation (Juni et al. 2001). Blinding of therapists and participants was not possible.
given the psychotherapeutic intervention. Attempting to blind assessors was disproportionate for the current stage of research. Statistician blinding was not possible in the current pilot study due to obvious differences in the data structure between intervention and control group, with additional process evaluation data collected from the intervention group only. Considerations that underlie the choice of control group are outlined in detail in Section 7.8.1.

RCTs can be classified along two dimensions: pragmatic to explanatory (Zwarenstein et al. 2008) and pilot / feasibility to definitive (Arain et al. 2010, Thabane et al. 2010). Considerations about the positioning of the WELLFOCUS Trial in relation to these two dimensions are now outlined.

**Pragmatic versus explanatory trials**

Trials described as ‘pragmatic’ are usually designed to inform service provision, e.g. to help choose between options for care. Their design aims to maximise external, or ecological, validity, i.e. the extent the results of the trial can provide a basis for generalisation to other circumstances (Juni et al. 2001). By contrast, ‘explanatory’ trials usually aim to test causal research hypotheses, e.g. particular biological changes due to a specific intervention, using trial designs that aim to maximise internal validity (Schwartz and Lellouch 1967).

Pragmatic and explanatory trials can be distinguished according to their (i) research question, (ii) setting, (iii) included participants, (iv) application of the intervention, (v) outcomes, and (vi) relevance to practice (Zwarenstein et al. 2008).

It has been suggested that pragmatic trials are usually conducted in routine practice settings, using little or no participant selection beyond the clinical indication of interest, specifically not excluding co-morbidities which may attenuate the treatment effect but are common in clinical practice. While they apply the tested intervention in a manualised fashion that allows fidelity evaluation, they may deliver it with some degree of flexibility, e.g. with respect to session timing, to reflect real world practice. By contrast, the highly controlled circumstances of explanatory trials include strictly defined settings that are often different from routine practice, and highly selected participants excluding the poorly adherent or those with co-morbidities. The application of the investigated intervention is strictly enforced and adherence is monitored closely. Both pragmatic and explanatory trials may focus on intermediate and process measures but pragmatic trials often use more practically relevant
endpoints as their main outcomes while explanatory trials are more likely to adopt short term surrogate outcomes (Zwarenstein et al. 2008).

Overall, pragmatic trial designs focus on effectiveness. They investigate whether an intervention works in the ‘real world’ in order to inform decision making in practice, and hence favour methodological choices that maximise external validity. Explanatory trials are primarily focussed on establishing the efficacy of the intervention, i.e. whether a specific intervention can work in a specific way (Thorpe et al. 2009). The distinction between effectiveness and efficacy may be relatively clear-cut for trials testing interventions such as medication for which the biological and clinical effects under highly controlled circumstances may clearly differ from the effects of the same drug when applied in routine settings. However, the distinction is not equally clear when it comes to complex psychological interventions with less well defined and less accurately measurable active ingredients and causal processes, especially in applied health services research working with clustered data and system level interventions. In the context of complex psychological interventions it has been argued that pragmatism and understanding mechanisms should not be viewed as mutually exclusive. Instead, a good complex intervention trial should answer both pragmatic and explanatory questions. It should test whether the intervention works and also explicitly consider how and why it works using multivariate outcomes, fidelity evaluation, and a careful analysis of moderating and mediating effects (Dunn 2013).

The WELLFOCUS Trial is a pragmatic trial with explicit attention to processes, as highlighted by the design choices in six areas (Thorpe et al. 2009, Zwarenstein et al. 2008):

1. Participants
   Setting: testing the intervention in a range of routine care settings
   Inclusion criteria: little participant selection beyond a clinical diagnosis of psychosis
2. Intervention
   Flexible application of intervention: Provided by potentially changing routine care therapists; participants being encouraged but not forced to attend; allowing to postpone up to two group sessions to the following week
   Practitioner expertise: the experimental intervention is applied by a range of practitioners with differing experience and in a range of settings
3. Comparison intervention: Usual care is used as the comparison group
4. Outcomes:
   Multivariate outcomes: including standard outcomes such as symptoms and
   functioning as well as psychological outcomes relevant to service users, i.e.
   wellbeing, and psychological surrogate outcomes for wellbeing
   Process evaluation: the trial includes comprehensive process evaluation

5. Compliance and adherence:
   Participant compliance: the trial uses unobtrusive measurement of compliance
   and no special strategies to enforce it
   Practitioner adherence: there is comprehensive but unobtrusive fidelity evaluation
   and no special strategies to enforce protocol adherence

6. Analysis: Intention to treat analysis is used

A detailed outline of the design choices in the WELLFOCUS Trial is provided in
Sections 7.2 to 7.10.

**Pilot versus feasibility studies**
The main aim of the WELLFOCUS Trial is to inform the design of a definitive RCT.
Such precursor studies, as recommended by the MRC (Craig et al. 2013), provide an
opportunity to identify and prepare for the challenges of evaluating an intervention and
will enhance the scientific rigour and value of the full-scale study (Feeley et al. 2009).
Precursor studies are usually called pilot or feasibility studies. Often no clear
distinction is made in the literature between what constitutes a pilot and what a
feasibility study (Lancaster et al. 2004), but there is concern that research described
as pilot or feasibility studies is often inadequately designed and reported (Arain et al.
2010). It has been suggested that studies which are underpowered for hypothesis
testing may often be relabelled as pilot studies (Halpern et al. 2002). However, both
feasibility and pilot studies have specific objectives which are different from definitive
RCTs (Arain et al. 2010). These objectives should be clearly described despite the
scientific challenge that there is no consensus on the distinction between feasibility
and pilot studies.

A literature review found that definitions of feasibility and pilot studies vary, but studies
labelled ‘feasibility’ tend to use a more flexible methodology compared to those
labelled ‘pilot’ (Arain et al. 2010). The authors suggested definitions for pilot and
feasibility studies:
**Feasibility studies** are undertaken before a main study to estimate important parameters necessary for designing the main study, such as the standard deviation of the outcome measure for sample size calculation, characteristics and feasibility of the outcome measures, willingness of people to be recruited and randomised, number of eligible participants, adherence, and follow-up rates. Feasibility studies should not evaluate the outcome of interest but instead be powered to estimate parameters such as recruitment or drop-out rates (Arain et al. 2010).

**Pilot studies** are a small version of the main study, run to ensure the components of the main study work together smoothly. They focus on the processes involved in the main study, e.g. recruitment, randomisation, treatment, and follow-up assessments. Pilot studies can be run as the first phase of the main study which may allow their results to be included in the overall analysis.

Other authors distinguish between internal and external pilot studies, where internal pilots somewhat correspond to what is termed pilot studies above, and external pilots more closely resemble feasibility studies according to the above definition (Lancaster et al. 2004).

**External pilot studies** are small studies which ideally focus on clearly defined feasibility objectives. Their results inform the planning of a main study. Common objectives for an external pilot study are to assess one or more of (Thabane et al. 2010, Lancaster et al. 2004):

1. the feasibility of key processes, such as eligibility criteria and their ascertainment, randomisation procedures and their acceptability, retention and refusal rates, failure/success rates, adherence, appropriateness of the primary outcome measure, or the acceptability of questionnaires
2. potential time and resource problems, such as administrative issues, staff training, the willingness and capacity of involved clinicians or centres, process times e.g. for postage, preparing equipment, dealing with contingencies such as material breakdown, clinician absence, or the like
3. potential human and data management problems, including space for personnel and data collection forms, data entry, and basic properties of the data such as missingness or variability
4. acceptability and safety of the intervention, dose, response, estimated treatment effect and estimated variance of the treatment effect for sample size calculation
5. the integrity of the study protocol
Internal pilot studies constitute the initial phase of a main study. The addition of an internal pilot allows the main study to be adapted based on the data generated in the pilot. Such adaptations usually follow decision rules that have been decided *a priori*. They may include, for example, changes to eligibility criteria, endpoints, the analysis plan, or, most commonly, the recalculation of the sample size for the main study (Thabane et al. 2010).

Studies containing an internal pilot phase share similarities with a group of methodological approaches called ‘adaptive trial designs’. However, adaptive trial designs encompass more than the initial part of a large study designated to identifying necessary adaptations. They allow modifications to be made to trial procedures or statistical analysis in an ongoing trial, ideally without undermining the validity and integrity of the study. However, adaptations do introduce specific challenges. Adaptive trial designs can be classified into three categories: prospective, concurrent (ad hoc), and retrospective (Chow and Chang 2008). Prospective adaptations are usually included into the overall trial design in an *a priori* fashion and include, for example, changes to randomisation, stopping early due to safety, futility or efficacy at interim analysis, or sample size re-estimation. Challenges include difficulties in making statistical inferences on treatment effect if randomisation rules are adapted mid-way through a trial, or the risk that statistically significant results are eventually produced instead of clinically relevant ones if sample size adjustments are made based on an interim analysis. Concurrent adaptations may include changes to inclusion criteria, dose or treatment duration, changes to hypotheses or study endpoints. They are usually not envisaged at the trial design stage but become necessary during its course and they carry significant risks, such as a shift in target population to a degree that does not reflect the initial aims of the study, the introduction of bias to data collection, or a loss of statistical power. Retrospective adaptations may include changes to the statistical analysis plan or the unblinding of treatment codes (Kairalla et al. 2012).

For pilot studies it has been suggested that the analysis should mainly be descriptive or focus on confidence interval estimates (Grimes and Schulz 2002). Data from an internal pilot may be included in the overall analysis of the main study. However, in order for that to be possible, key features of the main study need to be preserved in the pilot. For pilots of RCTs this includes identical blinding and randomisation procedures (Thabane et al. 2010). While it may be possible to estimate treatment
effects from an external pilot study, any conclusions from hypothesis testing should be
drawn with extreme caution since the limited sample size may lead to be misleading
or biased results (Thabane et al. 2010, Lancaster et al. 2004).

7.2 Design rationale and aims of the WELLFOCUS Trial

The WELLFOCUS protocol broadly focuses on the aims described for external pilot
studies (Thabane et al. 2010, Lancaster et al. 2004), but it also constitutes a stand-
alone study that aims to estimate important parameters necessary for designing a
definitive trial, as described for feasibility studies (Arain et al. 2010). A definitive
positioning of this study as feasibility and pilot is not possible due to the ambiguity in
the terms. In the remainder of this thesis the study will be referred to as a pilot study.

7.2.1 Design

This was a single centre pilot RCT to test WELLFOCUS PPT in a group format in a
convenience sample of people with psychosis. Patients were block randomised to
receive either WELLFOCUS PPT in addition to treatment as usual, or to continue to
receive treatment as usual only. The design of this pilot RCT has been informed by
recommendations for the conduct of pilot trials (Thabane et al. 2010, Lancaster et al.
2004). The trial was registered at Current Controlled Trials: ISRCTN04199273 -
WELLFOCUS study: an intervention to improve wellbeing in people with psychosis.

7.2.2 Objectives

The objectives of the WELLFOCUS Trial are: to pilot and optimise (1) the intervention,
(2) the trial processes, and (3) the evaluation strategy. The rationale in relation to
each is now outlined.

Objective 1: Piloting the intervention: To identify whether WELLFOCUS PPT is
feasible and acceptable and determine any necessary modifications.

WELLFOCUS PPT is a newly developed intervention which has not yet been applied
to any group of participants. One modification of standard PPT, based on a shorter
six-component manual and called ‘positive living’, has been tested with service users
with psychosis (Meyer et al. 2012), with a number of limitations (Section 3.2.6). The
comprehensive background research preceding the development of WELLFOCUS
PPT described in previous chapters led to the generation of a unique empirically
testable intervention and manual. Hence, even though ‘positive living’ may bear some
similarities with WELLFOCUS PPT, it does not allow conclusions with respect to the
acceptability and feasibility of WELLFOCUS PPT in people with psychosis in a UK mental health service setting. Hence the aim of testing the new intervention’s feasibility and acceptability and determining any necessary modifications is justified.

**Objective 2: Piloting the trial processes:** To test procedures for a future definitive RCT, especially in relation to eligibility criteria, randomisation procedures, allocation processes, and recruitment and retention rates.

It may be argued that the feasibility of trial parameters, such as recruitment, allocation, attendance or retention, can reasonably be inferred from trials testing different psychotherapeutic group interventions in a similar setting and client group. However, recruitment into group treatments in psychosis can be problematic (Richardson et al. 2007), and it is unclear whether the uniquely positive focus of WELLFOCUS PPT, which makes it distinct from other interventions, may additionally affect trial parameters such as willingness to participate or retention rates. This means it will be important to identify optimal recruitment and retention processes to inform a future definitive trial.

**Objective 3: Piloting the evaluation strategy:** To test approaches to assessing fidelity, process evaluation and outcome evaluation, in order to inform the design of a future definitive RCT including choice of primary and secondary outcome measures, and sample size calculation.

While in general the validity, reliability and feasibility is established for all of the applied measurement scales, there is no published research that would allow inferring their adequacy as primary and secondary outcome measures for WELLFOCUS PPT. Hence, a pilot study is needed to estimate parameters such as change in the chosen measures over time in the context of WELLFOCUS PPT, and the variability of the effect captured by the measures. The measurement strategies for process and fidelity variables were newly developed alongside the intervention model and manual. They need to be tested and potentially adapted for application in a definitive trial.

**7.3 Hypotheses**

While we conducted hypothesis testing, this was not the main objective of the pilot study but will be the purpose of the future definitive RCT. The reporting of the study does not therefore emphasise the results of hypothesis testing over the reporting of whether the objectives were met (Arain et al. 2010).
Our hypotheses were derived from the WELLFOCUS Model shown in Figure 6.2. Regarding the effect of the intervention, we hypothesised that participants receiving the intervention will experience, compared to the control group, an improvement in wellbeing (primary outcome) and good feelings, symptoms, connectedness, hope, self-worth, empowerment, and meaning in life (secondary outcomes).

7.4 Ethical approval

Ethical approval for the WELLFOCUS Trial was obtained from the Camberwell St Giles Research Ethics Committee (reference 12/LO/1960). R&D Approval was obtained from South London and Maudsley NHS Foundation Trust. Participants received verbal and written information, and written informed consent was obtained from participants before they enter the study. The research was conducted in compliance with the Declaration of Helsinki (WMA 59th General Assembly 2008).

7.5 Study setting

Patients were recruited from seven teams and two research registers across the South London and Maudsley NHS Foundation Trust (SLaM). SLaM employs 4,500 staff in 296 teams, works with 34,128 service users, and provides comprehensive mental health services across four Boroughs (Croydon, Lambeth, Lewisham, and Southwark) and specific mental health services across a further three Boroughs (Bexley, Bromley and Greenwich). These services are provided through diagnostic and age-based Clinical Academic Groups (CAGs). CAGs bring together clinical services, research, education and training for the benefit of patient care. This study took place in the SLaM Psychosis CAG.

7.6 Sample

**Inclusion criteria:** Patients were eligible to participate if they were aged 18-65 years, had a primary clinical diagnosis of psychosis, were using specialist mental health services, were not currently in prison, spoke and understood English, and in the opinion of their key clinician were sufficiently well to participate in a group therapy.

**Exclusion criteria:** Patients with serious cognitive impairment preventing meaningful participation in a group intervention, and those who in the opinion of their key clinician were unable to give consent or were too unwell to be interviewed.

More specific diagnostic inclusion and exclusion criteria were considered, such as comorbid substance abuse or personality disorders, or the establishment of a specific
research diagnosis. However, to maximise the relevance of the findings to inform the envisaged future definitive RCT, broad inclusion criteria were selected so as to reflect real world clinical practice.

### 7.7 Sample size

A sample size of n=30 per arm has been recommended for pilot studies to estimate location (mean) and variability (standard deviation) of candidate outcome measures to inform later sample size calculation (Lancaster et al. 2004). WELLFOCUS PPT was planned as a group intervention with about 8 participants in each group. Specifically, we aimed to conduct five waves of WELLFOCUS PPT groups versus control, each starting with 16 participants (n=8 in the intervention and n=8 in the control arm), giving a total sample of 80. Allowing for a drop-out rate of 20%, consistent with attrition in a feasibility study of a similar intervention with service users with psychosis (Meyer et al. 2012), this would provide an analysable sample of n=32 per arm to generate estimates for wellbeing as our primary outcome (as assessed with the WEMWBS).

The planned analyses were primarily descriptive and focussed on optimising trial and intervention parameters. However, additional analyses were planned to estimate the effect of the intervention according to the hypothesis that participants receiving the intervention will experience, compared to the control group, an improvement in wellbeing (primary outcome) and good feelings, symptoms, connectedness, hope, self-worth, empowerment, and meaning in life (secondary outcomes).

Table 7.1 outlines the power to detect a significant difference in mean wellbeing between intervention and control group at follow-up using an Analysis of Co-Variance (ANCOVA) with the expected sample size of 32 per arm, making different assumptions for the effect and the correlation of the outcome measure between baseline and follow-up.
Table 7.1: Power to detect a significant difference with the given sample size

<table>
<thead>
<tr>
<th>Correlation of outcome measure assumed for power calculation</th>
<th>Effect sizes assumed for power calculation</th>
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<tbody>
<tr>
<td></td>
<td>Small 0.2</td>
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<tr>
<td>weak</td>
<td>0.2</td>
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<tr>
<td>moderate</td>
<td>0.3</td>
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<td>strong</td>
<td>0.4</td>
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<td>Very strong</td>
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<td></td>
<td>0.7</td>
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<td></td>
<td>0.8</td>
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</tbody>
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With respect to the effect size, i.e. the difference between means at follow-up, we assumed a range of effects for WELLFOCUS PPT. For this purpose effect sizes were defined as small ($d=0.3-0.4$) medium ($d=0.5-0.6$), and large ($d=0.7$). For the correlation of the outcome measure between baseline and follow-up we assumed a range of Pearson correlations between weak ($r=0.2$) and very strong ($r=0.8$). Assumptions outside these ranges were regarded as unlikely or not meaningful and were hence not included in the analyses. For all calculations we assumed a significance level of 0.05.

Overall, this means that a sample size of 32 would be sufficient to detect an effect size of 0.7 given a pre-post correlation of the WEMWBS of at least 0.5, an effect size of 0.6 given a pre-post correlation of the WEMWBS of at least 0.7, and an effect size of 0.5 given a pre-post correlation of the WEMWBS of at least 0.8, with a power of 0.9 at a significance level of $p<0.05$.

### 7.8 Trial groups

#### 7.8.1 Background: control groups

Deciding on the control condition for a complex intervention in an RCT is challenging. A variety of different control conditions can be distinguished, all of which come with specific advantages and challenges.

At least three approaches to classifying control conditions can be identified from the literature. First, it has been suggested to distinguish three groups: withholding of treatment, usual care, and active treatment controls (Hart et al. 2007). Second, control conditions can be organised according to a hierarchy of their stringency, i.e. the
expected magnitude of the impact of exposure. The least stringent would be no
treatment and the most stringent an alternative active treatment, with other control
conditions such as waiting list, attention, or placebo in intermediate positions
(Freedland et al. 2011). Third, a distinction can be made between control groups and
comparison groups. Control groups aim to control for threats to internal validity due to
the impact of non-specific ingredients, while comparison groups aim to compare the
experimental intervention with a different active intervention. The stringency of the
control condition, i.e. the magnitude of impact it is designed or expected to have on
the outcome, also influences its usefulness as either a control or a comparison group.
While threats to internal validity can be controlled for using less stringent comparators,
active comparators also allow the establishment of superiority or inferiority of the
experimental treatment, although at the expense of a higher necessary sample size
(Mohr et al. 2009).

The choice of a particular control group depends on the overall aim of a trial. For
example, non-inferiority trials which aim to show that an experimental treatment is not
worse than a standard treatment will compare an experimental treatment with an
established one. Equivalence trials, aiming to show that two treatments are not too
different in outcome, will compare two established or two experimental treatments with
each other (Lesaffre 2008). The WELLFOCUS Trial is a superiority study, aiming to
show that one treatment (WELLFOCUS PPT in addition to routine care) is superior to
another (routine care alone). Hence treatment as usual is the appropriate comparator.

Practical and conceptual considerations to inform the choice of control conditions in
general are now outlined using the three categories of no-treatment, existing practice,
and active treatment comparators (Hart et al. 2007).

**No-treatment comparators**

Participants in a no-treatment control group receive all assessments but no
intervention. This controls for the effects of time, including spontaneous recovery and
contextual changes occurring during the same time period that may affect outcome
(Becker et al. 2003) and for the effects of repeated testing on outcome (Hart et al.
2007), including the improvement of scores because participants remember answers
from pre-test (i.e. testing effects), change that occurs because the questions asked in
the measurement tools encourage participants to change their behaviour (i.e.
reactivity to measurement), and the tendency of post-test scores to drift towards the
mean of the distribution (i.e. regression to the mean) (Becker et al. 2003). In practice,
no-treatment control groups are rarely feasible because treatment can either not be withheld for ethical reasons or it can simply not be ruled out that participants receive treatment from other providers (Freedland et al. 2011).

Another strategy to establish no-treatment comparison groups includes waiting lists which delay the receipt of experimental treatment until the experimental treatment has been completed in the intervention group. This controls for the effects of time and regression to the mean and also partly for expectancy effects. However, the effects of waiting conditions on outcome are complex and may only partly be attributable to specific mechanisms such as expectancy. Participants assigned to waiting conditions have both been shown to improve less than would be expected for spontaneous improvement, e.g. as measured in an observational study (Mohr et al. 2009), but also to improve more than would be expected for spontaneous improvement (Rutherford et al. 2012). Depending on the circumstances, control participants may also be used as a source of pre-post treatment data later which may save recruitment costs. In some cases waiting times may mirror the reality of services with waiting lists for specialised treatments. On the other hand, long waiting periods may also discourage participants from taking part in a study or increase drop-out rates (Hart et al. 2007).

It has been argued that placebo may also serve as a no-treatment condition, which does not only control for time and regression to the mean but also for some ‘non-specific’ treatment effects. Placebos are usually defined as harmless, completely inert and inactive, and closely resembling the active treatment, e.g. pill or medical procedure (Hart et al. 2007). Any effects of the placebo treatment are assumed to be due not to its physical properties but to psychological effects such as response expectancy (i.e. a directly self-confirming assumption which tends to produce the expected result, e.g. “When I take a pain-killer my pain will decrease”) or classical conditioning (e.g. pills acting as conditioned stimulus to produce a conditioned response mimicking the active treatment given repeated application). The magnitude of the placebo response has been shown to vary depending on the properties of the placebo, e.g. its colour, presentation, or time of administration, and the treated condition. For example both pain and depression show a particularly powerful response to placebo treatment (Kirsch 2005).

However, extending the concept of placebo from pharmacological treatments to psychotherapy is problematic. Unlike medication, psychological treatment has no physical properties. Hence, a psychological placebo would have to have the same
psychological properties as the real treatment but inert, otherwise it would be a
treatment of its own. Hence, practically it is impossible to develop a placebo matching
a psychotherapy intervention (Kirsch 2005). Proposed alternative solutions include
plausible but irrelevant treatment (also called sham treatment, pseudo treatment, or
spurious treatment), with the main challenge being the credibility of the sham
treatment which is often difficult to achieve (Hart et al. 2007). Another suggested
alternative is attention control where participants receive arguably non-therapeutic
attention such as phone calls to check how they are doing or additional data
collection. However, this does not account for expectancy effects and may not be
credible for participants over extended periods of time. Moreover, attention, together
with the relationship or alliance that develops with continued attention, may be
therapeutic in itself (Joyce et al. 2003). To avoid the effects of professional attention,
groups focusing on un-related outcome domains, such as dietary advice, may most
closely resemble what could be called a psychotherapy placebo.

**Existing practice comparators**

*Existing practice control groups* compare the experimental treatment with existing
(routine, non-study) treatments. Different and often ambiguous terminology is used in
the literature to describe these: *Treatment-As-Usual* (TAU) implies that the entire
population with the target problem routinely receives a particular treatment, which is
often not the case in reality. *Usual Care* (UC) does not imply that all target patients
routinely receive a specific sort of treatment but suggests a broader range of possible
treatments which may or may not be accessed by individuals. Often what is described
as TAU is UC in reality. *Standard Care* or *Routine Care* are further frequently used
and equally ambiguous terms to describe existing practice control groups (Freedland
et al. 2011).

The terms *Usual Care* and *Standard Care* describe different forms of existing practice.
*Usual Care* means that care providers independent of the research team determine
and provide the participant’s care. Variations to UC comparison groups include
enhanced or restricted UC which modify some aspects of care which control
participants receive by either adding or withholding specific components. This helps to
standardise UC to a lesser or higher extent depending on the scale of the add-ons or
restrictions (Freedland et al. 2011). In *Standard Care* control groups participants
receive a uniform guideline adherent treatment in a routine environment, which is only
possible in settings where such standardised treatment is effectively available and
where a uniform treatment protocol applies to all patients with the condition of interest (Freedland et al. 2011). This may not be the case in mental health care, where more individualised care plans are the norm rather than a uniform treatment of all patients with a certain diagnosis.

Control groups in general are usually designed to be as uniform as possible, e.g. everyone receiving the same placebo drug in the same manner. However, for UC control groups uniformity may not be achievable for three reasons: (i) non-study care may differ across participants due to them receiving care from different providers, different insurance covers, or different comorbid conditions; (ii) the quality of non-study care may differ across recruitment sites in that more complex, e.g. psychotherapeutic options may be available at some sites but not at others; and (iii) routine practices may change over time. These sources of within-group variability mean that that the simple descriptor such as TAU or UC may in reality mean different things to different participants in the same study (Freedland et al. 2011).

Comparing a new treatment directly to existing practice is most appropriate if the research question focuses on an aspect of care that is not addressed by routine care and if the experimental intervention can replace or augment routine care (Brigham et al. 2009). This means it may not be possible when the routine care involves an individualised multi-aspect multi-professional care plan as may be the case for people with severe mental disorders. In this case it would be more appropriate to choose an approach that superimposes the experimental treatment onto existing practice to establish its added value (Hart et al. 2007), as has been done in the WELLFOCUS Trial. In a definitive RCT this approach requires a higher sample size since the effect size of a new intervention on top of an established effective care package may be rather small. This is especially true when using an unrestricted UC approach in which participants in both treatment arms are allowed to access any form of routinely available therapy (Freedland et al. 2011), as is the case in the WELLFOCUS Trial.

The two major concerns raised in relation to UC comparators are that they do not control for differential attention from therapist time, and for expectancies, i.e. participants aware of their allocation to the active arm may have different expectations of improvement than control arm participants.

Attention bias may threaten a trial’s internal validity (Jensen et al. 2005), but it has also been questioned whether controlling for attention is possible, or indeed
necessary, in psychotherapy trials. Attention is a non-specific ingredient of any psychotherapy that involves a human therapist. This has two implications. First, there can never be content-free attention, since attention always needs a credible intervention to convey it to participants, which makes a pure attention control impossible. Second, if attention is an integral part of any psychotherapeutic intervention, its role as a threat to internal validity is questionable. In contrast to drug trials, in which attention is a co-administered ingredient that is at least theoretically independent from the effectiveness of the chemical compound under investigation, attention is not a rival explanation for the effectiveness of psychotherapy but simply one of its necessary ingredients (Freedland et al. 2011).

There is no clear distinction in the literature between non-specific therapy factors and placebo factors, as described earlier. Both usually include common factors in psychotherapy such as attention, therapeutic alliance, the discussion of presenting problems, cognitive restructuring, warmth, empathy, positive regard or response-contingent reinforcement (Kirsch 2005). Similar to attention, there is disagreement whether other non-specific factors should be controlled for in psychotherapeutic intervention studies. Some authors argue for a detailed exploration and differentiation of presumed active and non-specific factors in psychotherapeutic interventions, in the same way as levels of intensity or dose should be investigated (Jensen et al. 2005). Others maintain that all non-specific factors are simply therapeutic ingredients that do not need to be controlled for (Hart et al. 2007). The relevant question may not be what constitutes the active and what the non-specific effects but to determine the overall efficacy of a particular therapy, its reasons for effectiveness, its effects on different groups of recipients, and comparing it to alternative treatments. Such alternative therapies may range from ‘receipt of attention’ to any ‘specific therapy exercises’, but they should be regarded as a treatment rather than a non-specific control, given their predictable effect on recipients (Kirsch 2005).

Disagreement aside, investigating and potentially controlling for non-specific therapy effects is not an aim of early stage research. If an RCT shows that a novel intervention is superior to usual care, this may be partly due to an imbalance in the amount of clinical attention or other non-specific treatment factor. However, it does not really matter because the intervention could not have been delivered without those. The more important question may be if the outcome could also have been achieved with a less expensive or intensive intervention. This question can only be answered
with a comparative effectiveness study using an adequate control group. Such a study, however, will only be conducted at a later stage after the intervention has first been shown to be superior to usual care (Freedland et al. 2011).

The second major concern about UC comparators is their arguably missing control for differential expectation. Like attention, expectancy is an unspecific but active ingredient in any form of therapeutic intervention (Stice et al. 2007). If in a non-blinded trial two groups differ with respect to the treatment they receive and the outcome expectation they hold, expectation could bias treatment effects (Jensen et al. 2005).

Expectancy can occur in either arm and can be influenced by the nature of the intervention and the relationship with the treatment provider. For example, participants may expect greater benefit from the experimental intervention but they may equally have more confidence in their usual care provider with higher expectation in their established care. Also, people may participate in research for altruistic reasons or for monetary compensation and consequently prefer to end up in the usual care arm because it is less burdensome (Freedland et al. 2011). This implies that participant expectations may be only partially influenced by study design, and equivalent expectancies in all groups cannot be guaranteed even in highly standardised trials (Papakostas and Fava 2009, Rutherford et al. 2010). Expectancies, together with treatment preferences, should be assessed and evaluated in RCTs on psychotherapy interventions (Bower et al. 2005, King et al. 2005), but similar to addressing attention this is not an appropriate focus at an early stage of scientific development (Freedland et al. 2011), such as in the WELLFOCUS Trial.

To sum up, existing practice control groups come with numerous challenges, but they are also indispensable in effectiveness trials as they allow evaluation of whether a new intervention can augment or replace existing practice (Brigham et al. 2009). In fact, it has been suggested that the omnipresence of non-study care blurs the distinction between efficacy and effectiveness trials in behavioural studies, or explanatory and pragmatic methodologies. Both are usually conducted in real world settings but the kind of real-world setting may differ and with it the available non-study care, e.g. between a teaching hospital and rural community health clinic. Also, leading centres which have a lot to gain from positive results in terms of the ‘invented here’ credit may obtain results that are hard to replicate elsewhere. Excluding non-study care by exposing control participants to no treatment or placebo only may neither be ethical nor possible in any setting (Freedland et al. 2011).
Active comparison groups
Comparison groups that use active treatment as the control condition are usually useful at later stages in the research process. Such study designs may focus on research questions about the critical dose of an intervention or its active ingredients. Dose-control studies use comparison groups who receive the same experimental treatment but in lower doses expected to be less or not effective in order to establish the minimum necessary dose to achieve a proven effect. This approach can also be used in trials on complex interventions when the exact active ingredients of the experimental treatment are not known. In this case a very limited exposure to the experimental treatment may resemble a placebo control and is ethically defensible as well as credible to participants (Hart et al. 2007). In a dismantling design (Borkovec and Miranda 1999) a package of treatment components is compared to a similar condition containing more or fewer of the putative active ingredients. This approach is only possible if its ingredients are known and well defined. Hence, it can only be used for interventions that already have a strong evidence base. For studies using this design the research question would likely focus on the effectiveness of specific ingredients within an overall package (Hart et al. 2007). Equivalence trials are yet another approach. They test whether a new intervention is equally effective as an established intervention. While this may be highly acceptable to participants, it threatens the internal validity of the study since it no longer constitutes a control for any active ingredients but rather a comparison of two different packages of active ingredients. This limitation is less relevant when effectiveness for a treatment has already been established in comparison to a less stringent control group. All approaches comparing two or more active interventions require higher sample sizes to show a significant difference between study arms (Hart et al. 2007).

7.8.2 Rationale: control group choice for the WELLFOCUS Trial
A pilot trial that aims to test whether a new intervention is likely to have any effect at all cannot use a pure no-treatment control if any non-study treatment is available. It may use restricted UC but possibly at the expense of external validity (Freedland et al. 2011). Also, control group stringency usually increases as research progresses from early developmental to definitive RCTs (Mohr et al. 2009).

The WELLFOCUS Trial uses a TAU, or more precisely, a UC comparison group which allows participants in both study arms to concurrently receive any other treatment accessible through usual non-study care (Freedland et al., 2011). The control
condition was chosen to adequately match the current stage of research and to ensure proportionate use of resources. First, at this stage of scientific development the key question is whether WELLFOCUS PPT has benefits as an augmentation to standard care. If it were shown to be highly effective then an equivalence trial testing against another established treatment might be indicated. Second, an active comparator incurs costs which would be disproportionate at the current stage of research. Using a UC comparator will result in the most ecologically valid and conservative sample size estimate for the definitive RCT. Participants entering the WELLFOCUS psychotherapy are likely to generally agree to receiving psychotherapy, and they may also be more likely to enter alternative routinely available psychotherapeutic interventions. Especially, those in the control group may be more likely than those in the intervention group to take up a different therapy, simply because they have got more time available to do so. This reflects ‘real world’ conditions but it may dilute the results of the study and lead to lower effect sizes for WELLFOCUS PPT due to it actually being compared to a range of established interventions, as discussed in Section 9.2.

To establish the effect of additional routine treatments taken up by study participants, an adequate assessment of other attended therapies would have to be conducted, including a precise assessment of the nature, intensity and attendance rate of any other therapies. This was deemed inappropriate in the context of this pilot study. For a future definitive RCT informed by the results of the WELLFOCUS Trial, due consideration will have to be paid not only to the choice of the most adequate control group(s) but also to the assessment of potential confounders of treatment effects, as discussed in Section 9.5.

7.8.3 Control group

Control group participants received treatment as usual, consistent with the Care Programme Approach (CPA) (Department of Health 1999). This includes systematic arrangements for assessing the health and social needs of people accepted into specialist mental health services, the formation of a care plan which identifies the health and social care required from a variety of providers, the appointment of a key worker to keep in close touch with the service user and to monitor and co-ordinate care, and regular review and, where necessary, agreed changes to the care plan. Control group participants received care from a multidisciplinary mental health team, with interventions which may include medication, social or other individual or group-
based psychological interventions. No psychological intervention based on Positive Psychology principles was provided in the participating teams during the time of the WELLFOCUS Trial.

### 7.8.4 Intervention group

All intervention group participants received treatment as usual, as described for the control group, and in addition received WELLFOCUS PPT.

WELLFOCUS PPT was described in detail in Section 6.2.2. In brief, it comprises an 11-group intervention which aims to improve wellbeing in people with psychosis using ten exercises adapted from standard PPT (see Table 6.3). All intervention exercises target at least one of the four target areas identified in the WELLFOCUS Model (see Table 6.3).

WELLFOCUS PPT is provided by two therapists who follow the WELLFOCUS Manual. Groups last approximately 90 minutes, with a 10 minute break in the middle. Therapists are encouraged to show warmth, empathy and genuineness in their interactions. Therapists participate in all exercises themselves, they share personal examples from their own lives with the group, and are encouraged to do the Ongoing Exercise as well. Participants are not prohibited from sharing distressing, unpleasant, or negative states and experiences in the group. Negative contributions are validated but not focused on. Instead therapists establish a link between the negative experience and one or more of the intervention’s target areas. Participants in the intervention group receive a phone call between each session to offer support with the ‘ongoing exercise’. All therapists in the WELLFOCUS Trial had experience of facilitating therapeutic groups and of working with people with a diagnosis of psychosis. All therapists were invited to attend a monthly peer supervision meeting.

### 7.9 Measurement

#### 7.9.1 Outcome measures

One scale measuring overall subjective wellbeing was chosen as the primary outcome measure representing the distal outcome of wellbeing in the WELLFOCUS Model (see Figure 6.2). This was possible due to the recent development of an overall measure of wellbeing, i.e. the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), which integrates several of the pre-existing concepts and measurement tools for wellbeing. The 14-item scale frames wellbeing as a multi-dimensional construct (Tennant et al.
Items are rated on a five-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). The overall score is the sum of all items, ranging from 14 (low wellbeing) to 70 (high wellbeing). The WEMWBS shows adequate psychometric properties with Cronbach’s alpha between 0.87 and 0.91 and the one-week test-retest reliability at ŗ=0.83 (Tennant et al. 2007a, Clarke et al. 2011). Its validity was initially established in the UK general population (Tennant et al. 2007a) but it was subsequently used in various samples including, for example, students (Huppert and Johnson 2010), surgeons (Bartram et al. 2009), older people (Gale et al. 2011), or people with coronary heart disease (Tylee et al. 2011). While the scale has not been specifically validated with people with psychosis it was used in an RCT with clients with various mental health problems including some with psychosis, where it showed good sensitivity to change (Margrove et al. 2012). Secondary outcome measures cover the proximal outcomes of the WELLFOCUS model (i.e. the indicators of wellbeing in the dynamic framework), as described in detail in Chapter 7.

Twelve secondary outcomes were used.

1. The **Positive Psychotherapy Inventory (PPI)** consists of 25 questions rated on a five-point Likert scale ranging from 1 (not at all like me) to 5 (very much like me). The overall score is the sum of all items, ranging from 25 (low) to 125 (high). The scale contains five factors designed to assess positive emotions, engagement, relationships, meaning, and accomplishment (each with a total score between 5 and 25). It was specifically designed to capture changes due to Positive Psychotherapy in clients. The internal consistency of the scale was found at α=0.80 and test-retest reliability at ŗ=0.81 in a sample of healthy participants (Guney 2011).

2. The **Savouring Beliefs Inventory (SBI)** is a 24-item scale that assesses self-rated perceptions of three sub-scales: ability to derive pleasure through anticipating upcoming positive events, savouring positive moments in the present, and reminiscing about past positive experiences. It uses a seven-point Likert scale rated between 1 (strongly disagree) and 7 (strongly agree). The overall score is computed by summing responses to the 12 positively-anchored items and subtracting responses to the 12 negatively-anchored items. Total scores can range between -72 (low savouring beliefs) and +72 (high savouring beliefs) for the overall scale. Scores for the three subscales are calculated according to the same principle and can range from -24 to +24. The overall scale showed an internal consistency α=0.88 to 0.94 in different studies and a test-retest reliability
of $r=0.84$ (Bryant 2003). It was also found feasible to use in people with psychosis (Meyer et al. 2012).

3. The **Short Depression-Happiness Scale (SDHS)** measures affect on a bipolar continuum between depression and happiness (Joseph and McCollam 1993). It uses a 4-point Likert scale rated between 1 (never) and 4 (often). The six-item short version was found to have an internal consistency from $\alpha=0.77$ to 0.92 in different studies, and a test-retest reliability of $r=0.68$. The 3 positive items are reverse-scored which leads to overall scores ranging from 6 (more depression) to 24 (more happiness). Preliminary normative data suggest that a score of 9 may be indicative of mild but clinically relevant depression (Joseph et al. 2004).

4. The **Brief Psychiatric Rating Scale (BPRS)** is an 18-item observer-rated scale of psychiatric symptom severity (Overall and Gorham 1988). It uses a seven-point Likert scale rated from 1 (not present) to 7 (extremely severe). The overall score is the sum of all items, ranging between 18 (low symptoms) and 126 (severe symptoms). The internal consistency of the overall scale lies between $\alpha=0.65$ and 0.79, with sub-scales for withdrawal/retardation, thinking disorder, anxiety/depression, and activation varying between $\alpha=0.77$ and 0.88 (Crippa et al. 2002, Sanchez et al. 2005). Inter-rater reliability for the BPRS has been reported between 0.87 and 0.97. In terms of clinical interpretation, a BPRS total score of 31 was found to correspond to a clinical global impression rating of ‘mildly ill’, 41 to ‘moderately ill’, and 53 to ‘markedly ill’ (Leucht et al. 2005).

5. The **Integrative Hope Scale (IHS)** captures a comprehensive concept of hope and has been validated specifically in people with psychosis (Schrank et al. 2011, Schrank et al. 2012). The scale contains 23 items that are rated on a six-point Likert scale rated from 1 (strongly disagree) to 6 (strongly agree). The six negatively anchored items are reverse-scored. The overall score is the sum of all items, ranging between 23 (low hope) and 138 (high hope). Internal consistency is $\alpha=0.92$ for the overall scale, and test-retest reliability is $r=0.84$ in people with psychosis (Schrank et al. 2012).

6. The **Rosenberg Self-Esteem Scale (R-SES)** contains 10 items which are rated on a four-point Likert scale from 0 (strongly disagree) to 3 (strongly agree). The scale measures self-esteem by asking the respondents to reflect on their current feelings, with the 5 negatively anchored items being reverse-scored. The overall score is the sum of all items, ranging between 0 (low self-esteem) and 30 (high self-esteem). Its psychometric properties have been repeatedly established in
various client groups, including people with psychosis, and languages with the internal consistency found between $\alpha=0.77$ and 0.88 and the test-retest reliability between $r=0.82$ and 0.88 (Blaskovich and Tomaka 1991, Wowra and McCarter 1999).

7. The **Rogers Empowerment Scale (RES)** is a 28-item scale designed to measure subjective feelings of empowerment on a four-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). After reverse-scoring of the nine negatively framed items, the sum of all items forms the overall score which can range between 28 (low empowerment) and 112 (high empowerment). Its psychometric properties have been confirmed for people with psychiatric conditions, including psychosis, where the scale’s internal consistency was found at $\alpha=0.86$, and six of the seven factors of the scale showed a re-test reliability of $r>0.75$ (Rogers et al. 2010, Corrigan et al. 1999).

8. The **Sense of Coherence Scale (SCS)** contains 29 questions to measure a person’s global orientation to view the world and the individual environment as comprehensible, manageable, and meaningful. It uses a seven-point scale Likert scale rated between 1 (very seldom or never) and 7 (very often). 13 items are formulated negatively and have to be reversed for scoring. The overall score is the sum of all items, ranging between 29 (low sense of coherence) and 203 (high sense of coherence). In different samples and translations the scale showed an internal consistency of between $\alpha=0.70$ and 0.95 and a one year test-retest reliability from $r=0.69$ to 0.78 (Eriksson and Lindstrom 2006).

9. The **Manchester Short Assessment of Quality of Life (MANSA)** is an established 12-item scale that frames wellbeing in terms of subjective health related quality of life and includes a specific item asking for satisfaction with life as a whole (Priebe et al. 1999), which has been regarded as a measure of wellbeing in its own right (Cummins 1995). The scale is rated on a seven-point Likert scale ranging from 1 (couldn’t be worse) to 7 (couldn’t be better). The overall score is the mean of all item scores which can range between 1 (low satisfaction with life) and 7 (high satisfaction with life). The scale’s internal consistency was found between $\alpha=0.74$ (Priebe et al. 1999) and 0.81 (Björkman and Svensson 2005) in different samples of people with mental illness.

10. The **Health of the Nation Outcome Scale (HoNOS)** is a widely used 12-item scale of social disability. Items cover a range of problem areas rated on a five-point scale between 0 (no problem) and 4 (serious problem) with a resulting
overall score of up to 48. Cronbach’s $\alpha$ for the scale varies between 0.59 and 0.76 (Pirkis et al. 2005). The test-retest reliability was found to be mixed for HoNOS items, ranging between $r=0.65$ and 0.40 for seven items, and 0.31-0.32 for three items (Orrell et al. 1999).

11. The **Global Assessment of Functioning (GAF)** measures functioning. The scale is used in a two-item version assessing overall symptom severity and overall disability in the past month, each rated on a visual analogue scale from 1 (most serious symptoms or disability) to 90 (no symptoms or disability). The items show an internal consistency of between $\alpha=0.61$ and 0.91 and a test-retest reliability of between $r=0.66$ and 0.92 (Woldoff 2004).

12. The **CORE10** is a 10-item scale assessing symptoms. It is scored on a five-point Likert scale from 1 (not at all) to 5 (most or all of the time) resulting in overall scores between 10 and 50. The scale’s internal consistency is $\alpha=0.90$ (Barkham et al. 2013).

In addition, the **Sociodemographics Form - Service User (SF-SU)** was used at baseline. It is a non-standardised questionnaire modified from another RCT (Slade et al. 2011) which records the service user’s date of birth, gender, ethnicity, languages spoken, country of birth, education, employment, marital status, and housing (Appendix 4). At follow-up, those in the intervention group received a **Process Evaluation Questionnaire** which asks for the experience of all components of the WELLFOCUS Model (see Figure 6.2) using a 10-point Likert scale, shown in Appendix 5.

The rationale for inclusion of all standardised outcome measure is shown in Table 7.2.
### Table 7.2: Standardised outcome measures used in the WELLFOCUS study

<table>
<thead>
<tr>
<th>WELLFOCUS Model component</th>
<th>Measure</th>
<th>Rater</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distal outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal wellbeing</td>
<td>WEMWBS</td>
<td>Patient</td>
<td>Measures overall wellbeing, i.e. enhanced sense of self</td>
</tr>
<tr>
<td><strong>Proximal outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good feelings</td>
<td>SBI</td>
<td>Patient</td>
<td>Assesses pleasure in the past present and future, which are forms of good feeling addressed in the intervention</td>
</tr>
<tr>
<td></td>
<td>PPI positive emotions</td>
<td>Patient</td>
<td>Assesses enjoyment and happiness which are forms of good feeling addressed in the intervention</td>
</tr>
<tr>
<td>Symptom relief</td>
<td>SDHS</td>
<td>Patient</td>
<td>Measures depression, the reduction of which is an intended outcome of PPT</td>
</tr>
<tr>
<td></td>
<td>BPRS</td>
<td>Researcher</td>
<td>Measures general symptom severity including psychosis specific symptoms</td>
</tr>
<tr>
<td></td>
<td>CORE10</td>
<td>Patient</td>
<td>Measures general symptom severity</td>
</tr>
<tr>
<td>Connectedness</td>
<td>PPI relationships</td>
<td>Patient</td>
<td>Measures the presence of supportive relationships as a form of connectedness addressed in the intervention</td>
</tr>
<tr>
<td>Hope</td>
<td>IHS</td>
<td>Patient</td>
<td>Measures hope which is an indicator of wellbeing</td>
</tr>
<tr>
<td>Self-worth</td>
<td>R-SES</td>
<td>Patient</td>
<td>Measures self-worth which is an indicator of wellbeing</td>
</tr>
<tr>
<td>Empowerment</td>
<td>RES</td>
<td>Patient</td>
<td>Measures empowerment which is an indicator of wellbeing</td>
</tr>
<tr>
<td>Meaning</td>
<td>SCS</td>
<td>Patient</td>
<td>Measures meaning which is an indicator of wellbeing</td>
</tr>
<tr>
<td></td>
<td>PPI meaning</td>
<td></td>
<td>Provides a PPT specific measure of meaning</td>
</tr>
<tr>
<td><strong>Other outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of Life</td>
<td>MANS A</td>
<td>Patient</td>
<td>Quality of life is a form of wellbeing, allowing triangulation with the WEMWBS</td>
</tr>
<tr>
<td>Social disability</td>
<td>HoNOS</td>
<td>Researcher</td>
<td>To give opportunity to compare changes in wellbeing with social disability</td>
</tr>
<tr>
<td>Functioning</td>
<td>GAF</td>
<td>Researcher</td>
<td>To give opportunity to compare changes in wellbeing with functioning</td>
</tr>
</tbody>
</table>
7.9.2 Fidelity evaluation

Treatment fidelity refers to the methods applied to monitor and enhance the accuracy and consistency of an intervention in an intervention trial. Fidelity evaluation aims to evaluate the extent to which the intervention is implemented as planned and whether each component is delivered in a comparable manner to all study participants across time and treatment sites. Assessing treatment fidelity is important to inform considerations about internal validity, effectiveness and potential cost-benefit considerations (Smith et al. 2007).

The WELLFOCUS Trial used a framework for fidelity assessment that distinguishes five levels: study design, provider training, treatment delivery, treatment receipt, and skills enactment (Bellg et al. 2004).

Study design

Fidelity strategies at the design level aim to ensure that a study can adequately test its hypotheses, e.g. by using a theory driven intervention model, and establishing procedures to standardise the dose and intensity, prevent contamination and deal with implementation setbacks. We used three fidelity strategies at study design level:

1. We used an evidence-based testable intervention model, i.e. the WELLFOCUS Model.
2. To ensure the same treatment dose in all groups across the treatment arm, we sent treatment reminders, worked with fixed length group sessions and a fixed number of mid-week telephone contacts per participant. We used a treatment manual which is followed in each group and provided the same information material to every participant.
3. To address possible implementation setbacks, we maintained a pool of trained therapists, to avoid therapist absence leading to group cancellations.

By definition, all of these fidelity strategies apply to the design of the study and are not assessed in the fidelity evaluation.

Provider training

Fidelity strategies at the level of provider training aim to ensure adequate skill acquisition and skill maintenance of therapists. We used three fidelity strategies at the level of provider training:

1. We provided 1.5 days of standardised training for all therapists, led by the co-developer of standard PPT and the WELLFOCUS research team.
2. We provided monthly peer supervision sessions, which mirrored the groups’ therapist style and the focus on the four target areas as training boosters.

3. Both therapists were asked to jointly write PPT-style notes on participants’ achievements in the four target areas. This was intended to prevent therapeutic drift through practicing PPT style appraisal.

Implementation of all three strategies, i.e. attendance at training and peer supervision and compliance with joint session notes, was assessed in the fidelity evaluation of the WELLFOCUS Trial.

Treatment delivery
Fidelity strategies at the level of treatment delivery aim to ensure provision of identical content across the individual groups in the intervention arm and to minimise contamination between arms. We used two fidelity strategies at treatment delivery level:

1. We manualised the intervention, using unpublished best practice guidelines (REMINDE 2014).

2. Therapists were instructed to meet before each session to rehearse the session content as described in the manual, to minimise between-group differences.

The manualisation is described in Chapter 6, therapist compliance with the pre-session meeting was assessed in the fidelity evaluation of the WELLFOCUS Trial.

Treatment receipt
Fidelity strategies at the level of treatment receipt aim to ensure that participants understand and perform the cognitive and behavioural skills delivered during treatment. This is an important and often neglected component of fidelity. If participants do not understand or are not able to implement the new skills during treatment, an otherwise effective intervention may be deemed ineffective. We used two fidelity strategies at the treatment receipt level:

1. To ensure participant comprehension we used concise and plain English information materials supported by pictures in order to avoid a focus on literacy.

2. The Ongoing Exercise was supported and monitored by weekly telephone calls and reviewed in the subsequent group session to increase both understanding and implementation of the involved skills.

The first strategy was considered in the manualisation process, implementation of the second strategy was assessed in the fidelity evaluation of the WELLFOCUS Trial.
through assessing the number and lengths of telephone calls and using the researcher rated process and fidelity assessment form (Appendix 6).

Skills enactment

Fidelity strategies at the level of treatment skills enactment aim to ensure that skills learned during the therapy are adequately applied in real-life settings. Enactment is different from treatment adherence and treatment efficacy. Treatment adherence relates to whether a participant performs a task definitive of a specific treatment (e.g. actually notes down a good thing that has happened) and treatment efficacy relates primarily to whether an intervention influences the hypothesised endpoint. Treatment enactment specifically relates to the extent to which a participant actually implements a new skill in their everyday life. It is possible that a study shows excellent enactment but poor adherence and poor efficacy. This would provide a good test of the intervention because the treatment skills are used but are not effective. By contrast, in a study with poor enactment neither adherence nor efficacy is likely to be high. We used two fidelity strategies at the level of skills enactment:

1. Participants were repeatedly reminded throughout the duration of the group of skills learned during past group sessions to encourage their ongoing application, e.g. savouring small things in everyday life or noticing good things and collecting them in a Good Things Box.

2. The last manualised session focused on reflecting on the implementation of learned skills in everyday life.

Skill enactment was not assessed quantitatively, but mentioned in the qualitative process evaluation interviews and focus groups of the WELLFOCUS Trial.

Especially in trial designs that allow a level of flexibility it is important to be clear about the degree of change or adaptation that is permissible in order to be able to adequately record variations in implementation (Craig et al. 2013). The WELLFOCUS Trial allowed a small degree of pre-specified variation in the delivery and the implementation of the intervention. Permitted variability in the delivery included conducting certain exercises either in pairs or in the overall group depending on group size, adaptations of exercises in case of a physical handicap of participants (e.g. sitting instead of standing up), receiving a 15 minute recap of the last session either before a session or during the between-session phone calls in case a participant had missed a session, and offering people to keep the strength pictures used during the session in case they wanted. Permitted variability in the implementation included the
postponing of up to two sessions in case of low participation or lack of therapist availability, the use of up to four different therapists over the course of a group therapy, and a divergence of up to 15 minutes in the planned 90-minutes length of a session.

Fidelity evaluation does overlap with process evaluation both conceptually and practically in intervention trials (Craig et al. 2013). In the WELLFOCUS Trial the levels of provider training and treatment delivery were covered by fidelity evaluation strategies while the levels of treatment receipt and skills enactment were assessed as part of the process evaluation. An example section of the scale used to assess treatment delivery (adherence to treatment protocol), treatment receipt, and skills enactment, as well as the hypothesised processes according to the WELLFOCUS model is shown in Appendix 6.

7.9.3 Process evaluation

Complex interventions in health care by definition contain several interacting components. RCTs of such interventions are often considered a ‘black box’ and criticised for the lack of understanding they generate about why the intervention worked or not (Grant et al. 2013). Hence, the evaluation of a complex intervention in general should not only establish its effectiveness in practice, but also investigate how the intervention works, including its active ingredients and how they effect change (Craig et al. 2013). The questions of how and why an intervention works, of the processes that take place due to the intervention, as well as its potential mediators and moderators, are addressed in the process evaluation.

Process evaluations are studies that run alongside an intervention trial to explore the trial processes, and understand the underlying mechanisms with the aim of providing explanations for the trial results (Grant et al. 2013). Data for process evaluation can be both quantitative and qualitative (Oakley et al. 2006). The results of process evaluation can inform judgements about (Grant et al. 2013):

- the key components of the intervention
- connections between the intervention and outcomes and between the intervention and contextual or other factors associated with variations in outcomes
- implementation and study processes
- the utility of theoretical models underlying the intervention
- the generation of hypotheses for future research
The WELLFOCUS Trial used quantitative and qualitative process evaluation nested in the overall trial to test the intermediate processes outlined in the WELLFOCUS Model between the intervention (tested by fidelity assessment) and outcome.

**Quantitative process evaluation**

The co-therapist rated a quantitative process and fidelity measure, shown in Appendix 6, after each session. The measure covered seven assessment items relating to the treatment receipt and skills enactment level, which map onto the WELLFOCUS Model:

1. Presence of participants in group sessions (rated as yes or no)
2. Engagement of participants in exercises during treatment groups (rated as 0= not engaged, 1=somewhat engaged, 2=very engaged)
3. Therapist rating of whether session was perceived as beneficial by participant (rated as 0=not beneficial, 1=irrelevant/neutral, 2=beneficial, 3=very beneficial)
4. Therapist rating of participants’ behavioural intent to undertake the Ongoing Exercise, based on the session in which the Ongoing Exercise was set (rated as 0=no, 1=unsure, 2=yes)
5. Completion of Ongoing Exercise since last session (rated as 0=no, 1=fully or partly completed)
6. Therapist rating of feedback from participants on how the completed Ongoing Exercise had been experienced (rated as 0=not beneficial, 1=irrelevant/neutral, 2=beneficial, 3=very beneficial), based on the session in which the Ongoing Exercise was reviewed
7. Length and content of the weekly telephone calls.

Participants in the intervention group also received a short process evaluation questionnaire at follow-up that assessed elements from the WELLFOCUS Model, with all items rated on a Likert scale between 0 (not at all) and 10 (very much). This measure is shown in Appendix 5.

This pilot study tested the applicability of the WELLFOCUS Model in those who receive the intervention, but it did not assess potential contamination, i.e. whether those in the control arm of the study may have received parts of the experimental intervention and experienced intervention processes as well. Assessment of contamination will be conducted in a future definitive RCT. This will involve participants in all study arms being included in the process and fidelity evaluation.
Qualitative process evaluation

The qualitative process evaluation comprised individual interviews and focus groups with trial participants, and individual interviews with all involved group therapists. Participants were asked to take part in either an individual interview or a focus group, with the aim of applying the two methods alternately to consecutive groups. Those who had never attended a group session despite being randomised to the intervention group and those refusing to attend a focus group, were asked for an individual interview.

Service user participant interviews and focus groups had three aims: (i) to explore acceptability of the intervention, and identify suggestions for adaptations and improvements to the manual, (ii) to validate the model for increasing wellbeing through WELLFOCUS PPT, and (iii) to establish trial parameters. People who dropped out of the intervention arm or attended irregularly were asked for reasons including contextual factors influencing attendance, and for suggestions to improve attendance rates in the definitive RCT. The topic guide covering these areas is shown in Appendix 7. Therapist interviews had two aims: (i) to explore acceptability of the intervention, and identify suggestions for adaptations and improvements to the manual, and (ii) to establish trial parameters. In addition, therapists were asked about their views on therapist training and supervision and about contextual enablers and barriers for implementation. Specifically, the interviews also explored therapists’ experience of self-disclosure and participating in the Ongoing Exercise themselves.

7.9.4 Economic evaluation

An economic evaluation was considered, but evaluating the resource consequences of the intervention is more appropriate once the intervention has been finalised. Economic evaluation will be a goal for a future definitive RCT should WELLFOCUS PPT prove feasible.

7.10 Trial procedures

All researchers were trained by the primary investigator in the use of all standardised outcome assessments. Ongoing supervision for research staff was provided by the trial manager (BS).
7.10.1 Recruitment and randomisation

Two different approaches were used for recruitment. One recruitment route was through referral of eligible service users by staff from five community mental health teams and one rehabilitation inpatient service. The other recruitment route was through two research registers. Thus the sample constitutes a convenience sample. The judgement of each clinician regarding who to refer to the study may have involved different components, but the overall sample can still be regarded as representative because of the inclusion of a variety of routine service settings.

The study was introduced to all staff members in the participating teams. Care coordinators, key nurses or other appropriate staff members were asked to identify potentially eligible service users from their caseload. Potentially eligible participants received information about the study from the clinician. In addition, information about the study was sent to eligible service users on the two research registers (which involves prior consent to be contacted by researchers). These were followed up for recruitment via telephone by the research team. An appointment was scheduled for assenting participants from all sources with a member of the research team to provide further information on the study. In this meeting the study was explained, written information was provided, and an opportunity was given to ask any questions. If the participant wished to have time to consider participation, a second meeting was scheduled. Once the participant had given informed consent, baseline assessments were completed, comprising 11 participant rated and three researcher rated scales, as described in Section 7.9.1. Participants received an ID number which was entered in the web-based randomisation system together with age (for validation).

Some teams had fewer than 16 eligible participants. Hence, it was decided that the minimum number of participants for randomisation would be eight (i.e. four per arm). To compensate for the lower number of participants in some teams, we over-recruited up to a maximum of 20 participants in other teams. Randomisation was conducted in blocks of two or four simultaneously for all participants from a participating clinical team. Randomisation involved independent allocation to one of the two trial arms on a 1:1 basis. The use of stratification was considered disproportionate for a pilot RCT. The generation and implementation of the randomisation sequence was conducted independently by the King’s Clinical Trials Unit (registration number 053).
7.10.2 Assessment

Follow-up assessments were re-administered at the end of the intervention (i.e. three months after baseline), including the same questionnaires completed for baseline and the additional quantitative process evaluation form for intervention group participants. Every effort was made to include patients who had dropped out of treatment in the follow-up assessments in order to enable intention-to-treat analysis.

Process and fidelity measures were collected by the co-therapists for each participant after each group session using the researcher rated process and fidelity assessment form shown in Appendix 6, as well as by taking notes on phone calls and therapist compliance with fidelity strategies (outlined in Section 7.9.2) in an ongoing Excel spreadsheet. Qualitative process evaluation, i.e. either an interview or a focus group, was conducted with those in the intervention arm. Participants were offered £20 as compensation for their time after completing baseline and follow-up assessments and either the interview or focus group (i.e. £60 in total for intervention, £40 for control).

7.10.3 Approaches to minimise bias

It was not possible for service user participants or therapists to be blind to allocation status. The resources needed to ensure blinding research assessors were disproportionate for a pilot study. Therefore this trial was unblinded. However, several approaches were used to minimise bias.

Addressing bias at participant selection: The study used a convenience sample of service users considered fit to participate by clinical staff. While this may have led to selection bias, internal validity was protected by the random allocation strategy.

Addressing bias at allocation: All randomisation was undertaken by the independent King’s Clinical Trials Unit.

Addressing bias in baseline data: Baseline data were collected before allocation, to reduce assessment bias due to inadequate concealment.

Addressing bias in the intervention: Fidelity to the WELLFOCUS Manual was monitored to ensure comparability of the intervention between local groups.

Addressing bias in follow-up data: All participating services users were followed up and included in the analysis using an intention-to-treat approach to reduce the impact of selective attrition.
Addressing bias in outcome data collection: Bias in the outcome data was minimised by the use of standardised objective assessments and by rater training and supervision. Post treatment outcomes were, where possible, assessed by researchers who had not been involved in the participant’s baseline assessment or their WELLFOCUS PPT therapy group.

Addressing bias in process evaluation: As far as possible the focus group and interview data were collected by a researcher not involved in delivering the intervention to the participants, to minimise social desirability bias.

7.10.4 Data handling
All study data were entered into the database by the research workers who collected the data. Rigorous approaches to validating and verifying the data were used, including rater training to achieve an acceptable concordance in administering standardised assessments, development of a database with allowable values for variables as a validation check, and data verification and validation approaches as described in Section 7.11.1.

This study generated qualitative data comprising interview transcripts and associated analyses, and quantitative data from questionnaires and process evaluation forms. Protected data storage with clear access protocols in line with Good Clinical Practice Guidelines (MRC 1998) were used. Allocation and outcome data were stored separately. The only documentation which contained identifying material were the participants’ contact details and consent forms, which were stored separately from other study data with linkage through an ID number. A file linking the Participant ID number and personal data was password protected and stored on a secure server at the Institute of Psychiatry. Any audiotape recordings of qualitative data were destroyed once the transcription had been checked for accuracy. All paper forms of these data were stored in locked filing cabinets and electronic password-protected databases and documents at the Institute of Psychiatry. Only the research team had access to the non-anonymised data.

Electronic and paper data will be retained for 10 years. Exclusive use for primary research by the research team is envisaged for no more than three years following the study, to meet dissemination goals. Both the quantitative and qualitative data will be shared in anonymised form only. It is anticipated that the data may be used for secondary re-analysis as well as contributing to larger datasets. Archiving and
curating (including data sharing agreements and management of access rights) will be undertaken by the PI only and within the framework used by King’s College London, with due attention to issues of ethical (including consent and confidentiality aspects), legal and institutional regulatory permissions.

**Trial Management**

Prof Mike Slade (PI) had overall responsibility for the trial. The Trial Manager was Dr Beate Schrank, who was responsible for co-ordination and organisation of all trial related tasks.

**Risk and adverse events**

Relevant trust policies relating to potential areas of risk, such as risk management and medication, were adhered to. Serious adverse events were monitored by the Trial Manager and reported to the PI and the Trial Steering Committee in case of them possibly being linked to the trial.

**Trial supervision**

An independent Trial Steering Committee (TSC) was convened, comprising Stefan Priebe (Professor of Social Psychiatry, Queen Mary and Westfield College, London) (Chair), Jan Wallcraft (independent user researcher) and Michael Wright (funder representative). At the first TSC meeting the need for a Data Monitoring and Ethics Committee, interim analyses and stop rules for the trial were discussed. It was agreed that any serious untoward incident would be reported to the TSC Chair.

**7.11 Analysis**

**7.11.1 Data checking and cleaning**

Data checking and cleaning aims to ensure a high standard of data quality making any subsequent analyses trustworthy (Osborne 2013). It usually includes two stages: data verification, and data validation.

**Data verification**

Data verification assesses whether the responses given by participants are accurately represented in the electronic data file. This is necessary when data are transferred between sources, e.g. from paper questionnaires to an electronic database, which carries the risk of transcription errors. There are two standard procedures of data verification: double entry and proof-reading. Both were used for this study.
The full set of questionnaires for 20 (21.3%) participants, comprising 9,600 entries (480 variables per person), were double entered to detect transcription errors. Six non-systematic errors were identified, giving a concordance rate of 99.94%. For further quality assurance, two researchers manually checked the whole data set against the original paper questionnaires, i.e. proof-read all variables.

**Data validation**

Data validation aims to ensure the internal consistency of data based on pre-existing knowledge about the expected characteristics of the data set. In addition, data validation methods help to roughly estimate data quality. Data validation can involve four approaches: (i) prevention, i.e. not allowing bad data into a dataset in the first place; (ii) detecting, i.e. identifying defective data in a dataset; (iii) measuring the degree of defectiveness; and (iv) correcting detected defects (Lee and Wang 1993). For the present study, the approaches of detecting, measuring and correcting were applied.

**Detecting**

Defective data were detected using two indicators of data validity, i.e. completeness, and data spread. Completeness is important because an excess of missing responses might threaten the validity of summary scores. Hence the spread of missing responses was analysed, using descriptive statistics, in order to inform the decision on how to deal with missing responses. The spread of data is important because a deviation from the expected spread can be indicative of a response set, i.e. a tendency to exhibit a particular pattern of responses independent of the questions being asked, such as always choosing the highest or lowest option on a Likert scale (Lewis-Beck et al. 2003). A strong deviation from the expected data distribution, e.g. extreme skewness or an excess of outliers not found in other populations, could also indicate that a questionnaire is unsuitable for the client group. However, this was less of a concern in the present study since all questionnaires apart from the PPI had been validated for people with psychosis. Data spread was analysed by manually checking responses across the data set for unexpected distributions. Summary scores (overall and for sub-scales if applicable) were checked for outliers using box-plots, defining outliers as data points below or above the interquartile range. The Shapiro-Wilk test was applied to the overall summary scores of all questionnaires, to examine the null hypothesis that data show a normal distribution. One advantage of this test is that results are independent of sample size, a property which does not apply to alternative
tests of distribution such as the Kolmogorow-Smirnow-Test (Thode 2002). In addition, the distribution of all summary scores was visually checked for the entire study population as well as separately for intervention and control group using Q-Q plots.

**Measuring**

Data completeness was high. All bar two individual questionnaires had between zero and four single missing responses scattered randomly across the whole dataset. The MANSA showed 28 missing item responses from 94 completions at baseline and seven from 84 completions at follow-up. The IHS had 8 missing responses at baseline with one person incurring 5 missing responses. Apart from this one occasion, there were never more than 2 items missing per person on any scale. Generally, there were fewer missing responses in the follow-up compared to the baseline assessment. No pattern could be identified for missingness which was hence considered to have occurred completely at random, i.e. not related to the value of any other variable (Scheffer 2002).

No unlikely pattern of responses could be identified. Outliers were very rare with none at all in the WEMWBS, IHS, SDHS, RSES, CORE10, SBI, SCS, BPRS, and HoNOS. The MANSA showed a single outlier at baseline, the RES one at follow-up. The PPI overall showed two outliers at baseline and follow-up and up to four outliers in its sub-scales. This indicates that all questionnaires were appropriate for use in the given population.

Results of the Shapiro-Wilk test were significant for the IHS at baseline, and the PPI and BPRS at baseline and follow-up, indicating that these scores were not normally distributed. For all other questionnaires, the Shapiro-Wilk test confirmed a normal distribution. Visual inspection of the data did not suggest substantial skewness, indicating that overall the use of parametric statistical procedures was justified.

**Correcting**

We consulted published instructions for each measure but could not identify any specific recommendations for dealing with missing data. We therefore considered five standard methods: multiple imputation, last observation carried forward, imputing item-specific population means, pro-rating, and case deletion.

Multiple imputation, as the most robust solution was considered disproportionate for two reasons. First, the overall number of missing items was very low, and second, the
overall sample size of the study was small. A ‘last observation carried forward’ approach was not appropriate because of the lower number of missing responses at follow-up. Imputation of item-specific population means was considered not appropriate because it attenuates any correlations involving the variables that are imputed due to the lack of relationship between the imputed variable and any other measured variables, which makes it especially problematic for multivariate analysis (Scheffer 2002).

We decided to use pro-rating for up to a maximum of 2 missing items per scale. Pro-rating involves computing a mean score on the scale for an individual and imputing it into missing data fields. For scales with a positive and negative sub-set of questions (e.g. SDHS, SBI) we separately imputed means of the applicable sub-set. Pro-rating has advantages over imputing a population mean for the item because it more closely estimates the individual rating tendency. Assuming that there is a high degree of shared variance amongst the responses given by a specific person on an individual measure, pro-rating effectively uses what is known about the person to replace the missing value, and does not adversely affect statistical procedures (Enders 2010). For questionnaires with more than 2 missing responses we used case deletion, i.e. the entire questionnaire was excluded from the analysis. Only one measure (IHS) for one participant had to be deleted.

7.11.2 Qualitative analysis

Interviews and focus-groups were tape recorded, fully transcribed verbatim, and quality checked. The analysis involved a thematic analysis approach (Braun and Clarke 2006). The analysis process was led by BS and supported by other researchers. Specifically, the transcripts were repeatedly read to help the researchers familiarise themselves with the data. From the beginning of the open coding stage, the coding process was strongly informed by the content of the topic guide, by the structure of the intervention manual and by the hypothesised model. Data were organised in themes and clustered according to the analysis aims allowing the coding of individual text fragments into multiple categories. The coding frame was repeatedly discussed amongst the research team and subsequently refined. This involved merging or splitting codes and themes, identifying levels and relationships between them, and a repeated application of the emerging coding frame to the overall data set. Notes were taken throughout the whole process by all involved researchers and informed the interpretation of the data.
Results from the qualitative analysis of process evaluation data were integrated with results from quantitative statistical analysis to address the three study objectives.

### 7.11.3 Quantitative analysis

Divergence from normality was assessed for the distribution of all variables (as outlined in Section 7.11.1), as was linearity of correlations and equality of variance. Correspondingly, parametric statistical methods were applied throughout. Analyses were carried out using SPSS Version 20, Stata Version 12, and Excel Version 2010.

**Treatment effect**

Treatment effect was analysed in addition to the three objectives of the pilot trial. Unadjusted changes between baseline and follow-up were calculated separately for intervention and control group using significance testing with paired sample t-tests. ANCOVA analysis was chosen for the intention to treat (ITT) analysis. ANCOVA determines whether there are any significant differences between the means of two or more independent groups whilst statistically controlling for other variables. This allows inferences about whether any change is due to the group (i.e. intervention vs. control) whilst simultaneously assessing and controlling for the effect of any number of confounders, both continuous and categorical, on the dependent variable (Leech et al. 2011). An ANCOVA is often preferred over change analysis because it may be more efficient and resistant to bias (Senn 2006). A separate ANCOVA was performed for each of the outcome measures at follow-up, to compare the intervention and control group whilst adjusting for the respective measure’s baseline value. An additional ANCOVA was run for each outcome, adjusting not only for baseline score but also for therapy group to control for effect modification. Standardized effect sizes (Cohen’s $d$) were calculated. Therefore, first the pooled standard deviation (SD) was calculated from the unadjusted mean differences at follow-up generated with t-tests using group as the independent variable. Then Cohen’s $d$ was calculated in MS Excel using the formula “(Adjusted follow-up mean in intervention group – adjusted follow-up mean in control group) / pooled SD”. A further sensitivity analysis controlled for the influence of the known prognostic factors of age and gender.

**Objective 1: Piloting the intervention**

Acceptability of the intervention was assessed by statistically exploring compliance patterns, including attendance rates, completion rates, proportion of homework completed and rate of loss to follow-up. The influence of therapy group and basic
participant characteristics on attendance rates, completion rates and loss to follow-up was explored using Analysis of Variance (ANOVA) and linear regression analyses. The quantitative results were combined with results from the qualitative process evaluation to suggest recommendations for specific adaptations to the intervention components and their delivery. Both quantitative and qualitative process evaluation was used to investigate whether the processes and changes subjectively experienced by participants correspond with the processes outlined in the WELLFOCUS Model. For the quantitative process evaluation, percentages were calculated for completion of Ongoing Exercise, and means were calculated and transformed to percentages for all other variables in the researcher rated and the participant rated process evaluation scores to facilitate comparison.

**Objective 2: Piloting the trial processes**

Descriptive analysis was used to assess (i) eligible participants, (ii) consent rates in relation to referral, (iii) waiting times, (iv) the randomisation procedure, (v) and receipt of intervention as allocated. Those receiving and not receiving the intervention were compared on participant characteristics using t-tests and chi² tests. Average waiting times between referral, consent and start of the therapy were calculated and analysed in relation to drop-out status using ANOVA. Qualitative data from researcher, therapist and participant feedback were used to supplement quantitative data in order to explain non-participation, the acceptability of the randomisation procedure, discrepancies between allocation and receipt of intervention, and therapist drop-out.

**Objective 3: Piloting the evaluation strategy**

The usefulness of fidelity and process evaluation approaches was determined using both descriptive and inferential statistics (ANCOVA and linear regression) to estimate their value for predicting outcome and attendance as compared to recording group attendance only. The confidence interval (CI) approach was used to help determine the suitability of the outcome measures for a definitive RCT. This approach involves estimating the CI of the difference between intervention and control group at follow-up, adjusted for baseline. Results showing the CI to cross zero (i.e. point of no effect) and/or a value representing a clinically relevant effect help to estimate the suitability of measures for a definitive RCT (Lancaster et al. 2004). Further considerations to inform the choice of outcome measures included the acceptability of scales (as measured by the number of missing responses), the overall variance of scales, and the magnitude of correlation between baseline and follow-up.
In order to calculate the sample size needed for a definitive RCT, the expected mean in the intervention group was additionally calculated from Cohen’s d (from ANCOVAs adjusted for baseline and therapy group) and the pooled SD using the formula “d * SD + mean of control group”. Sample sizes were then calculated using information on the expected means, the pooled SD and the correlation between baseline and follow-up.

In order to make the sample size calculation more generalizable, i.e. less tied to the specific circumstances of the present study, the mean of the control group was standardised to 10 for all sample size calculations (using the STATA command `sampsi` “mean in control group (set to 10)” “expected mean in intervention group”, p(power term) sd(pooled) method(ancova) r01(correlation baseline follow-up) pre(1) post(1), e.g. for the WEMWBS: `sampsi 10 10.14, p(0.8) sd(0.793) method(ancova) r01(0.581) pre(1) post(1)`.)
Chapter 8: Results

This chapter describes the results of the pilot RCT and the nested process evaluation. It presents the sample characteristics (Section 8.1), treatment effects (Section 8.2), and the results of the analyses pertaining to the three objectives, i.e.: piloting the intervention (Section 8.3), piloting the trial processes (Section 8.4), and piloting the evaluation strategy (Section 8.5).

8.1 Sample characteristics

The flow diagram for study participants is shown in Figure 8.1.

**Figure 8.1: Participant flow in the WELLFOCUS Trial**

Baseline characteristics for the 94 randomised participants are shown in Table 8.1, separately for intervention and control group.
## Table 8.1: Sociodemographic and baseline clinical characteristics (n=94)

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Mean (SD)</th>
<th>Control</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td>43 (11.0)</td>
<td>42 (11.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male</td>
<td>26 (55.3)</td>
<td>30 (63.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td>White</td>
<td>21 (44.7)</td>
<td>23 (50.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-White</td>
<td>26 (55.3)</td>
<td>23 (50.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Birth Place</strong></td>
<td>UK-born</td>
<td>29 (61.7)</td>
<td>27 (57.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Accommodation</strong></td>
<td>Owned</td>
<td>8 (17.0)</td>
<td>4 (8.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rented</td>
<td>27 (57.4)</td>
<td>34 (72.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>12 (25.5)</td>
<td>8 (17.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship Status</strong></td>
<td>Single</td>
<td>39 (83.0)</td>
<td>42 (89.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>in Partnership</td>
<td>8 (17.0)</td>
<td>5 (10.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Qualifications</strong></td>
<td>None</td>
<td>5 (10.9)</td>
<td>2 (4.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secondary education (11-16 years)</td>
<td>11 (25.6)</td>
<td>16 (34.8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further education (16-18 years)</td>
<td>11 (25.6)</td>
<td>12 (26.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Higher education (18+)</td>
<td>12 (26.1)</td>
<td>10 (23.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relevant professional training</td>
<td>7 (15.2)</td>
<td>6 (13.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td>Working or studying</td>
<td>10 (21.3)</td>
<td>10 (21.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not working</td>
<td>37 (78.7)</td>
<td>37 (78.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Years using mental health services</strong></td>
<td></td>
<td>13 (11.0)</td>
<td>14 (11.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)</strong></td>
<td></td>
<td>3.19 (0.76)</td>
<td>3.00 (0.89)</td>
<td></td>
</tr>
<tr>
<td><strong>Manchester Short Assessment of Quality of Life (MANSA)</strong></td>
<td></td>
<td>4.05 (0.85)</td>
<td>4.14 (1.01)</td>
<td></td>
</tr>
<tr>
<td><strong>Positive Psychotherapy Inventory (PPI)</strong></td>
<td></td>
<td>3.58 (0.73)</td>
<td>3.44 (.80)</td>
<td></td>
</tr>
<tr>
<td><strong>Brief Psychiatric Rating Scale (BPRS)</strong></td>
<td></td>
<td>30.70 (8.81)</td>
<td>33.57 (8.42)</td>
<td></td>
</tr>
<tr>
<td><strong>Short Depression-Happiness Scale (SDHS)</strong></td>
<td></td>
<td>2.29 (0.69)</td>
<td>2.48 (0.76)</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Outcomes in Routine Evaluation Scale (CORE-10)</strong></td>
<td></td>
<td>2.55 (0.67)</td>
<td>2.79 (0.68)</td>
<td></td>
</tr>
<tr>
<td><strong>Integrative Hope Scale (IHS)</strong></td>
<td></td>
<td>4.02 (0.79)</td>
<td>3.72 (0.85)</td>
<td></td>
</tr>
<tr>
<td><strong>Rosenberg Self-Esteem Scale (RSES)</strong></td>
<td></td>
<td>2.24 (0.64)</td>
<td>2.09 (0.66)</td>
<td></td>
</tr>
<tr>
<td><strong>Savouring Beliefs Inventory (SBI)</strong></td>
<td></td>
<td>4.80 (1.22)</td>
<td>4.48 (1.02)</td>
<td></td>
</tr>
<tr>
<td><strong>Rogers Empowerment Scale (RES)</strong></td>
<td></td>
<td>2.74 (0.32)</td>
<td>2.71 (0.32)</td>
<td></td>
</tr>
<tr>
<td><strong>Sense of Coherence Scale (SCS)</strong></td>
<td></td>
<td>4.18 (1.05)</td>
<td>3.81 (1.11)</td>
<td></td>
</tr>
<tr>
<td><strong>Health of the Nation Outcome Scale (HoNoS)</strong></td>
<td></td>
<td>7.29 (5.05)</td>
<td>9.62 (5.19)</td>
<td></td>
</tr>
<tr>
<td><strong>GAF</strong></td>
<td></td>
<td>62.37 (15.79)</td>
<td>57.43 (16.35)</td>
<td></td>
</tr>
</tbody>
</table>

There were no significant differences (assessed using $\chi^2$ or t-tests as appropriate) between the groups on any variable except for HoNOS which differed at $p=0.03$. 

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8.2 Treatment effect

No adverse events were reported during the WELLFOCUS study and no participant wanted or had to stop taking part in the intervention due to any harmful effects of WELLFOCUS PPT.

8.2.1 Raw data on change

As an initial step, unadjusted changes between baseline and follow-up were calculated separately for intervention and control group. Results are shown in Table 8.2, organised according to the components of the WELLFOCUS Model.
Table 8.2: Changes from baseline to follow-up (n=84)

<table>
<thead>
<tr>
<th>Model component</th>
<th>measure</th>
<th>Group</th>
<th>Mean difference (CI)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distal outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wellbeing</td>
<td>WEMWBS</td>
<td>CONTROL</td>
<td>0.15 (-0.10-0.41)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.26 (0.06-0.45)</td>
<td>0.010</td>
</tr>
<tr>
<td><strong>Proximal outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good feelings</td>
<td>Savouring Beliefs (SBI)</td>
<td>CONTROL</td>
<td>0.05 (-0.16-0.27)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.08 (-0.15-0.32)</td>
<td>n.s.</td>
</tr>
<tr>
<td>PPI positive emotions</td>
<td></td>
<td>CONTROL</td>
<td>-0.05 (-0.27-0.16)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.17 (-0.03-0.37)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Symptom relief</td>
<td>Depression (SDHS)</td>
<td>CONTROL</td>
<td>-0.07 (-0.22-0.09)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>-0.24 (-0.45--0.03)</td>
<td>0.028</td>
</tr>
<tr>
<td></td>
<td>BPRS</td>
<td>CONTROL</td>
<td>0.78 (-1.16-2.72)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>-2.51 (-4.70--0.32)</td>
<td>0.026</td>
</tr>
<tr>
<td></td>
<td>CORE-10</td>
<td>CONTROL</td>
<td>-0.07 (-0.22-0.07)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>-0.08 (-0.22-0.07)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Connectedness</td>
<td>PPI relationships</td>
<td>CONTROL</td>
<td>0.03 (-0.14-0.20)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.16 (-0.01-0.32)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Hope</td>
<td>IHS</td>
<td>CONTROL</td>
<td>0.19 (-0.02-0.41)</td>
<td>0.080</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.21 (0.00-0.42)</td>
<td>0.048</td>
</tr>
<tr>
<td>Self-worth</td>
<td>Rosenberg Self-esteem scale (R-SES)</td>
<td>CONTROL</td>
<td>0.05 (-0.07-0.18)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.19 (0.04-0.34)</td>
<td>0.016</td>
</tr>
<tr>
<td>Empowerment</td>
<td>Rogers empowerment scale (RES)</td>
<td>CONTROL</td>
<td>0.01 (-0.07-0.08)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.07 (-0.01-0.16)</td>
<td>0.079</td>
</tr>
<tr>
<td>Meaning</td>
<td>Sense of Coherence Scale</td>
<td>CONTROL</td>
<td>0.17 (-0.03-0.36)</td>
<td>0.088</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.24 (0.01-0.46)</td>
<td>0.040</td>
</tr>
<tr>
<td></td>
<td>PPI meaning</td>
<td>CONTROL</td>
<td>0.08 (-0.08-0.25)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.17 (0.01-0.33)</td>
<td>0.036</td>
</tr>
<tr>
<td><strong>Other outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>MANS A</td>
<td>CONTROL</td>
<td>0.11 (-0.07-0.30)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.34 (0.11-0.57)</td>
<td>0.004</td>
</tr>
<tr>
<td>Social disability</td>
<td>HONOS</td>
<td>CONTROL</td>
<td>-0.37 (-1.91-1.18)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>0.03 (-1.38-1.44)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Functioning</td>
<td>GAF</td>
<td>CONTROL</td>
<td>1.82 (-2.93-6.56)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERVENTION</td>
<td>3.73 (-0.70-8.16)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

*p* significance testing with paired sample t-tests
### 8.2.2 Intention to treat analysis

A separate ANCOVA was performed for each of the outcome measures at follow-up, to compare the intervention and control group whilst adjusting for the respective measure’s baseline value. Results are shown in Table 8.3 together with the standardised effect sizes (Cohen’s d).

#### Table 8.3: ANCOVA analysis for all outcome variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean score at follow-up adjusted for baseline (CI)</th>
<th>Adjusted mean difference between groups at follow-up (CI)</th>
<th>Significance level of group effect</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRIMARY OUTCOMES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEMWBS</td>
<td>3.36 (3.17-3.56)</td>
<td>3.24 (3.04-3.44)</td>
<td>0.13 (-0.16 – 0.41)</td>
<td>p=0.374</td>
</tr>
<tr>
<td><strong>SECONDARY OUTCOMES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SBI</td>
<td>4.74 (4.53-4.94)</td>
<td>4.64 (4.43-4.85)</td>
<td>0.09 (-0.20 - 0.39)</td>
<td>p=0.532</td>
</tr>
<tr>
<td>PPI</td>
<td><strong>3.73 (3.60-3.87)</strong></td>
<td><strong>3.50 (3.37-3.64)</strong></td>
<td><strong>0.23 (0.04 - 0.42)</strong></td>
<td><strong>p=0.018</strong></td>
</tr>
<tr>
<td>SDHS</td>
<td>2.14 (1.98-2.31)</td>
<td>2.35 (2.18-2.51)</td>
<td>-0.21 (-0.44 - 0.03)</td>
<td>p=0.090</td>
</tr>
<tr>
<td>BPRS</td>
<td><strong>29.43 (27.52-31.34)</strong></td>
<td><strong>33.28 (31.33-35.24)</strong></td>
<td><strong>-3.86 (-6.60 - -1.12)</strong></td>
<td><strong>p=0.006</strong></td>
</tr>
<tr>
<td>CORE-10</td>
<td>2.58 (2.45-2.71)</td>
<td>2.66 (2.53-2.79)</td>
<td>-0.08 (-0.27 - 0.11)</td>
<td>p=0.407</td>
</tr>
<tr>
<td>IHS</td>
<td>4.11 (3.92-4.31)</td>
<td>4.04 (3.84-4.25)</td>
<td>0.07 (-0.22 - 0.36)</td>
<td>p=0.622</td>
</tr>
<tr>
<td>R-SES</td>
<td>2.37 (2.24-2.51)</td>
<td>2.21 (2.08-2.35)</td>
<td>0.16 (-0.03 - 0.35)</td>
<td>p=0.094</td>
</tr>
<tr>
<td>RES</td>
<td>2.81 (2.74-2.88)</td>
<td>2.74 (2.67-2.81)</td>
<td>0.07 (-0.03 - 0.18)</td>
<td>p=0.158</td>
</tr>
<tr>
<td>SCS</td>
<td>4.24 (4.05-4.43)</td>
<td>4.10 (3.91-4.30)</td>
<td>0.14 (-0.14 - 0.41)</td>
<td>p=0.315</td>
</tr>
<tr>
<td>MANSA</td>
<td>4.41 (4.21-4.60)</td>
<td>4.19 (3.98-4.39)</td>
<td>0.22 (-0.07 - 0.50)</td>
<td>p=0.132</td>
</tr>
<tr>
<td>HoNOS</td>
<td>8.20 (6.88-9.53)</td>
<td>8.59 (7.24-9.95)</td>
<td>-0.39 (-2.31 - 1.52)</td>
<td>p=0.684</td>
</tr>
<tr>
<td>GAF</td>
<td>64.83 (60.71-68.95)</td>
<td>61.75 (57.53-65.97)</td>
<td>2.62 (-3.41 - 8.65)</td>
<td>p=0.390</td>
</tr>
</tbody>
</table>

**bold:** p<0.05

On all scales, changes reflect more improvement in the intervention group compared to the control group. No effect of group was found on the primary outcome (WEMWBS). Significant improvements were found for the PPI and BPRS only.

In order for an ANCOVA to be valid, nine assumptions have to be fulfilled (Leech et al. 2011, Lund and Lund 2013): (1) the dependent variable should be measured on a continuous scale, (2) the fixed factor should consist of two or more categorical, independent groups, (3) observations should be independent, i.e. there should be no relationship between the observations within or between the groups, (4) there should be no significant outliers, (5) the dependent variable should be approximately normally distributed for each category of the independent variable, (6) there should be homogeneity of variances, (7) the covariate should be linearly related to the
dependent variable at each level of the independent variable, (8) there should be homoscedasticity and (9) there should be no interaction between the covariate and the independent variable.

Assumption (1), (2), (4) and (5) were shown to be fulfilled in Section 7.5.1. Assumption (3) was fulfilled in the control but not the intervention group. WELLFOCUS was provided as a group therapy, making participants within a therapy group more alike than those from different groups. Clustering in just one arm of the trial is a known problem which is often insufficiently attended to in the published literature of trials comparing group interventions to treatment as usual and should ideally be addressed by clustering the analysis in one arm (Dunn 2013). This was regarded as disproportionate for a pilot trial and unlikely to yield meaningful results due to the limited sample size.

Assumption (6) was checked using Leven’s test for homogeneity. Results were non-significant for all variables indicating that the assumption of homogeneity of variances was met. Assumption (7) was highly likely to be met since the dependent and independent variables effectively constitute paired assessments. However, for completeness the relationship was checked by plotting the baseline measure of each scale against the follow-up measure separately for the intervention and control group using scatter plots. This confirmed the assumed linear relationships. Assumption (8) was checked by plotting scatterplots of the standardised residuals against the predicted values. The plots were generally randomly distributed across the entire range of possible values, indicating that the assumption of homoscedasticity was met.

Finally, assumption (9) was tested by adding an interaction term between the independent variable (intervention vs. control group) and the covariate (baseline scores) for each analysis separately. Results showed a significant interaction between group and baseline score for all variables, indicating that the assumption of homogeneity of regression slopes was violated. However, an interaction between group and outcome is highly likely in intervention studies, since due to the nature of the research design participants in one group (i.e. the intervention group) are expected to change more than those in the control group. Hence, the assumption of homogeneity of regression slopes is less relevant for this study design (Leech et al. 2011). In addition, it has been shown that the results of an ANCOVA are robust to the violation of this assumption when group sizes are equal (Hamilton 1977), which is the case in the present study.
8.2.3 Adjusted analysis

To account for effect modification by therapy groups, an additional ANCOVA was run for each outcome, adjusting not only for baseline scores but also for therapy group. Therapy group had a significant effect on the BPRS and SBI, but on no other outcome variable. Correspondingly, the results changed only marginally after adjustment.

Results of the analyses adjusted for therapy group and baseline scores are shown in Table 8.4 together with the standardised effect size (Cohen’s d) for each outcome.

Table 8.4: ANCOVA analysis adjusted for baseline values and therapy group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (n=43)</th>
<th>Control (n=41)</th>
<th>adjusted mean difference between groups at follow-up (CI)</th>
<th>Sig. level of group effect</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEMWB</td>
<td>3.37 (3.17-3.57)</td>
<td>3.23 (3.03-3.44)</td>
<td>0.132 (-0.15 – 0.42)</td>
<td>p=0.552</td>
<td>0.18</td>
</tr>
<tr>
<td>SBI</td>
<td>4.75 (4.55-4.95)</td>
<td>4.63 (4.43-4.84)</td>
<td>0.116 (-0.17 – 0.40)</td>
<td>p=0.426</td>
<td>0.11</td>
</tr>
<tr>
<td>PPI</td>
<td>3.74 (3.60-3.87)</td>
<td>3.50 (3.36-3.64)</td>
<td>0.235 (0.04 – 0.43)</td>
<td>p=0.017</td>
<td>0.30</td>
</tr>
<tr>
<td>SDHS</td>
<td>2.14 (1.97-2.30)</td>
<td>2.35 (2.18-2.52)</td>
<td>-0.209 (-0.45 – 0.03)</td>
<td>p=0.085</td>
<td>0.29</td>
</tr>
<tr>
<td>BPRS</td>
<td>29.36 (27.49-31.22)</td>
<td>33.36 (31.45-35.27)</td>
<td>-4.001 (-6.68 – -1.32)</td>
<td>p=0.004</td>
<td>0.43</td>
</tr>
<tr>
<td>CORE10</td>
<td>2.58 (2.45-2.71)</td>
<td>2.66 (2.53-2.80)</td>
<td>-0.082 (-0.27 – 0.11)</td>
<td>p=0.387</td>
<td>0.13</td>
</tr>
<tr>
<td>IHS</td>
<td>4.12 (3.92-4.32)</td>
<td>4.04 (3.83-4.25)</td>
<td>0.077 (-0.21 – 0.37)</td>
<td>p=0.597</td>
<td>0.09</td>
</tr>
<tr>
<td>R-SES</td>
<td>2.38 (2.24-2.51)</td>
<td>2.21 (2.08-2.35)</td>
<td>0.162 (-0.03 – 0.35)</td>
<td>p=0.092</td>
<td>0.25</td>
</tr>
<tr>
<td>RES</td>
<td>2.81 (2.74-2.89)</td>
<td>2.74 (2.67-2.81)</td>
<td>0.074 (-0.03 – 0.18)</td>
<td>p=0.154</td>
<td>0.22</td>
</tr>
<tr>
<td>SCS</td>
<td>4.25 (4.05-4.44)</td>
<td>4.10 (3.91-4.30)</td>
<td>0.144 (-0.13 – 0.42)</td>
<td>p=0.302</td>
<td>0.14</td>
</tr>
<tr>
<td>MANSA</td>
<td>4.41 (4.21-4.61)</td>
<td>4.18 (3.98-4.38)</td>
<td>0.230 (-0.06 – 0.51)</td>
<td>p=0.112</td>
<td>0.23</td>
</tr>
<tr>
<td>HoNOS</td>
<td>8.16 (6.84-9.48)</td>
<td>8.64 (7.29-9.99)</td>
<td>-0.477 (-2.38 – 1.43)</td>
<td>p=0.619</td>
<td>0.09</td>
</tr>
<tr>
<td>GAF</td>
<td>66.16 (61.96-70.36)</td>
<td>63.39 (59.09-67.70)</td>
<td>2.766 (-3.27 – 8.80)</td>
<td>p=0.365</td>
<td>0.17</td>
</tr>
</tbody>
</table>

Bold: p<0.05

Using the standard effect size categories for Cohen’s d, the effect size found for the PPI and BPRS can be regarded as medium, while all other effect sizes were small.

8.2.4 Sensitivity analysis

A further analysis controlled for the influence of the known prognostic factors of age and gender (Sin and Lyubomirsky 2009). For this purpose, the participant who defined their gender as neither male nor female was removed from the data set, giving a sample of 83 participants.

Adjusting for age and gender slightly improved the results for all scales. It led to the SDHS also being significantly improved in the intervention compared to the control group (p=0.049) but did not change the significance levels of the results for any other scale below p=0.05.
8.3 Objective 1: Piloting the intervention

Objective 1 of the WELLFOCUS Trial was to identify whether WELLFOCUS PPT is feasible and acceptable for the new client group of people with psychosis and to determine any necessary modifications.

8.3.1 Feasibility and acceptability

Attendance rates

WELLFOCUS PPT was provided to six groups with a mean of eight (range four to ten) participants. The mean attendance rate was 54% of sessions (range 38% to 80%). ANOVA revealed that attendance rates were independent from therapy group. Linear regression showed that gender did not predict attendance rates. However, participant age significantly predicted attendance rates, with higher age predicting better attendance, and higher BPRS scores at baseline also predicted better attendance. In the univariate analyses, age accounted for 19% and BPRS scores for 9% of the variance in attendance rate. Entering both significant predictors simultaneously in a linear regression model to estimate their combined predictive effect resulted in an $R^2$ of 0.23 but rendered BPRS scores insignificant.

Across the 11 therapy sessions, attendance rates ranged between 38.3% and 68.1%, with session 1 (Introduction to WELLFOCUS) being the most well attended and session 7 (Forgiveness 1) the most frequently missed.

Completion rates

Completion was defined as having attended at least 50.0% (i.e. six) of the therapy sessions. A total of 26 (55.3%) of the 47 participants randomised to the intervention group were completers. Reasons stated by intervention group non-attenders for non-attendance included mental health relapse or physical illness (n=5), hospital or GP appointments (n=5), being otherwise occupied (n=5), the location being difficult to reach (n=3), transport costs (n=2), family needs (n=2), disorganisation (n=2), lack of motivation (n=2), anxiety of attending group sessions (n=1), delusions and voices preventing attendance (n=1), not getting on with other people and lack of enjoyment of the first session (n=1), misunderstanding the nature of the study (n=1), and not being reminded by hostel staff to attend (n=1).

Therapist feedback reflected similar barriers to attendance for participants, including the location of certain groups, transport issues, difficulties with time management and
motivation, perceiving others to be at a different stage in the recovery process, difficulty understanding English, and not getting on with other people in the group.

**Completion of ongoing tasks**
Completion of ongoing task ranged between 41.2% and 95.0%, with the ongoing task for session 3 (Good things) being most frequently completed and the one for session 9 (One door closes, another door opens) least frequently completed.

**Loss to follow-up**
Four participants from the intervention group and six from the control group were lost to follow-up. The difference in the proportion of drop-outs was not significant (z=0.669, p=0.503). Separate one-way ANOVAs revealed that neither age nor baseline BPRS predicted drop-out. A chi\(^2\) test showed no significant difference in the distribution of gender between those who dropped out and those who did not. Overall there was no evidence of substantial or selective attrition.

**8.3.2 Validation of the WELLFOCUS Model**
Quantitative process evaluation was conducted in two ways: (i) co-therapists completed a process evaluation questionnaire on each participant in each session, and (ii) participants in the intervention group completed a process evaluation questionnaire during the follow-up assessment. Qualitative process evaluation additionally explored participants’ subjective experience of the hypothesised active ingredients.

**Researcher rated process evaluation**
Table 8.5 shows researcher rated process evaluation scores for each therapy group and overall.
## Table 8.5: Researcher process evaluation

<table>
<thead>
<tr>
<th>Process component</th>
<th>Rating on process evaluation measure (%)</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engagement in intervention exercises in session</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>79.0</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>77.5</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>90.0</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>82.0</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>86.0</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>92.0</td>
<td></td>
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<tr>
<td>Overall</td>
<td>85.0</td>
<td></td>
</tr>
<tr>
<td>Exercises in session experienced as beneficial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>67.3</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>61.3</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>65.7</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>68.7</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>76.0</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>75.7</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>69.3</td>
<td></td>
</tr>
<tr>
<td>Intent to undertake exercise outside session</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>86.0</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>94.5</td>
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<tr>
<td>Group 3</td>
<td>54.5</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>60.0</td>
<td></td>
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<tr>
<td>Group 5</td>
<td>78.0</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>91.0</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>79.0</td>
<td></td>
</tr>
<tr>
<td>Exercises undertaken outside the session</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>77.6</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>54.3</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>59.4</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>50.0</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>66.7</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>67.9</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>63.9</td>
<td></td>
</tr>
<tr>
<td>Exercise outside the session perceived as beneficial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>80.0</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>70.3</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>66.7</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>68.3</td>
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<td>Group 5</td>
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<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>69.3</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>72.0</td>
<td></td>
</tr>
</tbody>
</table>

### Participant rated process evaluation

Results for participant rated process evaluation questions are shown in Table 8.6, organised by group.

## Table 8.6: Participant process evaluation

<table>
<thead>
<tr>
<th>Model component</th>
<th>Rating on process evaluation measure (%)</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing positive experiences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>85.7</td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>68.6</td>
<td></td>
</tr>
<tr>
<td>Group 3</td>
<td>65.0</td>
<td></td>
</tr>
<tr>
<td>Group 4</td>
<td>68.6</td>
<td></td>
</tr>
<tr>
<td>Group 5</td>
<td>42.0</td>
<td></td>
</tr>
<tr>
<td>Group 6</td>
<td>61.4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>66.5</td>
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</tr>
<tr>
<td>Amplifying personal strengths</td>
<td></td>
<td></td>
</tr>
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</tr>
<tr>
<td>Total</td>
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</table>

Chapter 8: Results
Overall, participant ratings were consistently lower than researcher ratings. Group 1 showed consistently higher and Group 5 consistently lower ratings than the other four groups. This difference was not reflected in the researcher rated process evaluation.

**Qualitative process evaluation**

The qualitative process evaluation confirmed participants’ perspectives that WELLFOCUS PPT had indeed had a positive influence on the four intended target areas. Some illustrative examples are given below.

Target area 1: Increasing positive experiences

WELLFOCUS PPT (and especially the way in which activities were planned, carried out and then reflected on) was reported to have given confidence and motivation to try new things, avoid negative thoughts, gain a new positive outlook, and encourage people to get the most out of experiences in terms of enjoyment and pleasure. The strengths and savouring sessions led to renewed interest in and enjoyment of hobbies that may have been neglected and improved concentration.

Target area 2: Amplifying strengths

Participants generally agreed that WELLFOCUS PPT had helped them not only to identify their strengths but also to use them and reflect on their experiences positively, which resulted in a gain in confidence and self-worth. Two participants were able to apply for or enter voluntary employment, which they attributed to their newly gained positivity and belief in their strengths.

Target area 3: Fostering positive relationships

WELLFOCUS PPT was reported to have helped develop new and improve existing relationships, e.g. through being more open and willing to share both problems and positive experiences, increased awareness of own values, or more conscious appreciation of relationships. Several participants said they had been able to share with their family what they had done in the sessions, and consequently benefited from their family supporting them with exercises. Two participants cited improved relationships with their children and newly gained pleasure of spending more time with them.

Target area 4: Creating a more meaningful self-narrative

It was a general perception amongst participants that WELLFOCUS PPT had fostered a more positive outlook on the self and life, associated with feeling more confident and
comfortable, and being more open to new activities, ideas and relationships. Further gains included finding meaning and motivation for future planning, developing more realistic expectations and a more positive, constructive attitude which helped to relax and cope better with problems.

8.3.3 Suggested changes

Participants and therapists also extensively commented on the specific content of WELLFOCUS PPT and suggested a number of adaptations to optimise it for the needs of people with psychosis.

Suggestions and requests were considered against the following criteria:
1. Does it increase the acceptability of the intervention? (acceptability requirement)
2. Is it consistent with the rationale and basic premise of PPT? (treatment integrity requirement)
3. Is it capable of being delivered by standard resources? (pragmatic requirement)

Three superordinate themes were identified from the feedback which met the three criteria set out above: optimising understanding and maintenance; optimising for the client group; and optimising therapist involvement. Examples of suggestions which did not meet the criteria included holding an expenses-paid group bonding weekend at the seaside for service-users, or having custom made designer workbooks for participants to collect therapy materials. Suggestions and requests fulfilling each of the criteria were incorporated into a revised manual for WELLFOCUS PPT, as discussed in Section 9.2.

Optimising understanding and maintenance

Suggestions in this area included (i) providing a clearer rationale of WELLFOCUS PPT, (ii) maximising the use of key tools, and (iii) translation of therapeutic changes into daily life. A clearer rationale might be provided in an additional introductory session, covering the therapeutic approach, especially when it comes to dealing with problems and negative issues, potential benefits for participants at different stages of recovery, and the concept and purpose of between-session telephone calls and ongoing exercises. To support the use of key tools and transfer acquired skills into daily life, more time should be spent discussing the purpose of the WELLFOCUS journal and how to continue using it after the sessions have finished. More repetition in general, more time for the regular recap of previous sessions, giving participants
the chance to lead the mindful-savouring of music, and designated discussion of maintenance strategies would also contribute to the skills transfer.

**Optimising for the client group**

Suggestions in this area pertained to (i) further reducing cognitive demands, (ii) providing a clear structure, (iii) preparing the ongoing exercises, and (iv) reducing anxiety. Cognitive demands may be reduced by slowing down the pace of the therapy, by introducing additional sessions and providing more time for repetition, further simplifying the worksheets, and leaving more space for discussion of difficult topics. Improvements in the structure might include reinforcing the rules of attendance, or replacing paired activities and role-plays with whole-group exercises and joint discussion. More time was requested for discussing the rationale and purpose behind each individual exercise and for preparing and starting each Ongoing Exercise in the sessions. This might increase the likelihood of participants picking an appropriate and valuable task, encourage them to make concrete plans, and increase their confidence to approach it. Reducing anxiety was a major issue for many, which may be dealt with in the introductory session and also openly discussed throughout the course of the therapy.

**Optimising therapist involvement**

Additional therapist training, discussion of therapist involvement in the WELLFOCUS PPT exercises, and preparation for therapist self-disclosure was requested, as was more background information on the rationale of the exercises and working materials. Between-session telephone calls were suggested to be more valuable if always done by the same person, ideally the therapist also conducting the groups.

### 8.4 Objective 2: Piloting the trial processes

Objective 2 of the WELLFOCUS Trial was to establish the feasibility of the trial processes to inform a future definitive RCT.

**Eligible participants**

Recruitment took place in eight teams and via two routes. In two specialist psychosis community services holding registers of service-users interested in participating in research, letters were sent out to potentially eligible participants and followed up by telephone calls. In five community mental health teams and one inpatient
rehabilitation service, 47 care-coordinators referred potential participants. Recruitment was started with a target sample of n=80. Interest in WELLFOCUS PPT was unexpectedly strong, leading to a higher than expected recruitment rate and consequently to an over-recruitment of a total of 94 participants.

Recruitment and consent rates
The mean overall consent rate was 40.17%, comprising 35.9% for the referrals by care co-ordinators and 81.81% for people contacted via research registers. Overall, 124 people declined to take part in the study at initial contact. Reasons given for non-consent were: dislike of groups (n=26); timing (n=19); location (n=12); dislike of questionnaires (n=16); no interest in PPT (n=13); no need for therapy in general (n=5); no experience of psychosis (n=1); and already doing another therapy (n=1). Twenty-six participants did not provide a reason. Six participants who originally expressed interest could not be reached again.

Randomisation procedure
There were no significant differences between the groups at baseline, except for HoNOS scores (Table 8.1). Feedback from participants on the process of randomisation was generally positive. It was described as well explained and accepted as a necessary part of the study. Two participants felt the randomisation procedure was not fair and ways of dealing with allocation to non-preferred arms should be discussed before randomisation.

Waiting times
The average waiting time between referral and baseline assessment (i.e. consent) was 18.6 days (SD 12.9), between baseline assessment and the first group session 11.7 days (SD 4.2), and between referral and the first group session 30.3 days (SD 14.2). Those lost to follow-up did not significantly differ from other participants in terms of waiting times.

Receipt of intervention as allocated
Four participants allocated to the intervention group never attended a single session. One could not be contacted after randomisation, and reasons for non-attendance given by the other three participants were time of the therapy sessions, being generally too busy, and physical illness.
8.5 Objective 3: Piloting the evaluation strategy

Objective 3 was to test approaches to assessing fidelity, process and outcome evaluation, to inform the design of a future definitive RCT including choice of primary and secondary outcome measures, and sample size calculation.

8.5.1 Fidelity evaluation

*Fidelity at the level of provider training*

Fidelity assessment at the level of provider training included (i) therapist training, (ii) attendance at the monthly peer supervision sessions, and (iii) joint notes taken after each session about each participant’s achievements and strengths to counter therapeutic drift.

All therapists took part in a 1.5-day training course, contributed to adapting the manual in the expert consultation meeting, and gave ongoing advice on the evolving manual adaptation. Overall, attendance at peer supervision was 60.7% (range 0% to 100% for individual therapists). The main reasons for non-attendance were timing and location of the supervision group. Suggestions for improving therapist attendance included timing after regular working hours; choosing an easily reachable location; paying therapists for attendance (e.g. on an all-or-nothing basis); making supervision mandatory; and changing its image to an exciting opportunity to learn in a hospitable environment. Joint notes were completed after 60% of sessions, ranging from 30% in Group 3 to 100% in Groups 1 and 2.

*Fidelity at level of treatment delivery*

In order to ensure equal treatment delivery across the therapy groups, therapists were instructed to meet before each session to discuss the manual and the delivery of its content. Therapist compliance with this meeting was 100%.

*Fidelity at level of treatment receipt*

Fidelity assessment at the level of treatment receipt included: (i) receipt of between-session phone calls, (ii) number of different therapists providing the groups, (iii) number of session cancellations and postponed sessions, and (iv) content coverage in individual therapy groups.

Between-session phone calls were received by 59.8% of eligible participants (ranging from 50.3% in Group 5 to 81.2% in Group 1). Between two and four therapists were involved in the provision of one course of therapy, with 82.0% of groups delivered by
the two initially assigned therapists. All sessions were given, but a total of three (4.5%) of the 66 sessions had to be postponed due to low attendance and annual leave of therapists. Content coverage was 97.2% on average (range 83.4% to 100%). Where content was not covered it was almost exclusively the savouring exercise at the beginning and the end, mainly due to problems with participant punctuality which disrupted the exercise.

8.5.2 Usefulness of fidelity and process evaluation strategies

Usefulness of fidelity evaluation
Separate ANCOVAs for the six therapy groups revealed WEMWBS scores at follow-up adjusted for baseline of between 3.0 and 3.6. In the overall ANCOVA, therapy group was not a significant predictor of outcome. No obvious pattern could be identified in the fidelity evaluation that may have corresponded with change in wellbeing in the individual groups.

Usefulness of researcher and participant rated process evaluation
To compare the usefulness of the researcher and participant rated process evaluation, all items in the respective assessments were averaged to create one new variable for each process evaluation method. They were then entered separately in linear regression analyses with WEMWBS at follow-up as the dependent variable adjusted for baseline. Session attendance was separately used as the predictive variable in an analogous regression.

None of the independent variables significantly predicted WEMWBS at follow-up, but participant rated process evaluation showed a trend towards significance at p=0.06. Additional linear regression analyses explored whether the two ways of measuring processes predicted attendance, based on the assumption that better engagement and experience of benefit might predict adherence to the therapy. Both were significantly predictive of attendance, with the participant rated process evaluation explaining 21% and researcher rated process evaluation explaining 97% of the variance in attendance. However, attendance and research rated process measures were highly significantly correlated at r=0.99, i.e. they effectively measure the same underlying variable. This explains the very high explanatory power of researcher rated process measures in the linear regression model and makes it an unsuitable tool to predict attendance, or outcome on top of attendance.
8.5.3 Appropriateness of outcome measures

As described in Section 7.11.1, missing responses were rare overall and only one questionnaire (the IHS) had to be excluded on one occasion due to more than 2 missing items. Outliers were very rare with most scales showing none, and the MANSA, RES and PPI between one and four at either baseline or follow-up. This indicates that the scales are understandable and acceptable to the client group.

Confidence interval approach

The confidence interval (CI) approach focuses on the estimation of treatment effects (with associated errors) and the specification of a clinically important effect size. Since hypothesis testing is not the main aim of a pilot trial this is an alternative approach which allows estimation of whether changes on a specific scale are likely to generate meaningful results in a definitive trial. If the mean adjusted difference between intervention and control group at follow-up shows change in the right direction and the confidence interval of the difference includes a clinically meaningful value, the scale may yield appropriate results in a definitive trial with an adequate sample size.

For the confidence interval approach, mean differences adjusted for baseline and for therapy group (as described in Section 8.2) were used. The point estimates (adjusted mean differences between groups at follow-up) and confidence intervals (CI) for all standardised outcome scales are displayed in Table 8.3. All differences between intervention and control group pointed in the expected direction, i.e. wellbeing associated variables show higher while symptom related variables show lower levels in the intervention group. Except for the BPRS and the PPI, all confidence intervals cross zero with the SDHS showing a borderline result (i.e. CI close to zero). The question of whether the confidence intervals include values of meaningful change remains for discussion (see Section 9.2).

Correlation between baseline and follow-up

All scales showed highly significant correlations (paired sample t-tests) between baseline and follow-up. The strength of the correlation was .56 for GAF, .58 for WEMWBS, .61 for HoNOS, .65 for SDHS, .68 for RES, .71 for HIS and for BPRS, .75 for CORE-10, .76 for MANSA, .77 for RSES, .80 for SBI and for SCS, and .83 for PPI.
8.5.4 Sample size calculation for definitive RCT

The sample size needed for a definitive RCT was calculated using the expected mean in the intervention group, the pooled SD and the correlation between baseline and follow-up for each outcome measure. Sample sizes are shown in Table 8.7 for each scale, assuming a power of 0.80 and a significance level of 0.05.

Table 8.7: Sample sizes for each candidate outcome measure

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<thead>
<tr>
<th>Scale</th>
<th>Pooled SD</th>
<th>Expected mean</th>
<th>Baseline to follow-up correlation</th>
<th>Sample size in each arm</th>
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Chapter 9: Discussion

9.1 Summary of the thesis

This thesis adapted Positive Psychotherapy for people with psychosis and tested the adapted intervention – WELLFOCUS PPT – in a pilot randomised controlled trial with service users with psychosis. The research process followed the MRC guidance for the development and evaluation of complex interventions (Craig et al. 2008).

Aim 1: The first aim of the thesis was to develop a theory-based and testable model of wellbeing for people with psychosis. This aim was met through a systematic literature review and narrative synthesis (Chapter 4) and a qualitative study (Chapter 5). The systematic literature review characterised the evidence base relating to wellbeing in people with psychosis and developed the static framework of wellbeing as a new conceptual structure to organise components of wellbeing potentially relevant for people with psychosis. The static framework was used as the starting point for identifying potential targets for an intervention to increase wellbeing. Qualitative methods were then applied to understand the experience of wellbeing and the processes of change involved in improving it. The resulting dynamic framework of wellbeing served as the basis for developing the intervention model to be tested in the pilot RCT.

Aim 2: The second aim of the project was to develop and manualise an intervention to increase wellbeing for people with psychosis. The usefulness of Positive Psychotherapy for people with psychosis and suggested changes to adapt the intervention for the new client group were elicited in the qualitative study. Decisions for changes were supported by expert consultation, and the standard PPT manual was adapted into WELLFOCUS PPT (Chapter 6). The WELLFOCUS PPT manual and the WELLFOCUS Model were developed accordingly.

Aim 3: The third aim of the project was to undertake a pilot RCT to evaluate the intervention with people with psychosis. The methodology for the pilot RCT (Chapter 7) was based on guidelines for the conduct of pilot trials (Lancaster et al. 2004, Thabane et al. 2010). The adapted intervention was evaluated with service users with
psychosis recruited from the South London and Maudsley NHS Foundation Trust (Chapter 8).

Aims 1 and Aim 2 were discussed in Chapters 4 to 6. The results of the pilot RCT addressing Aim 3 are now discussed.

### 9.2 Discussion of WELLFOCUS Trial

Results of the ITT analysis showed a non-significant effect of the intervention on the main outcome of wellbeing (according to the WEMWBS) and most secondary outcome measures, except for the BPRS and the PPI. More positively, the change was in the intended direction for all outcome measures, and the intervention was well received by clients and enjoyed by therapists. Adaptations to optimise WELLFOCUS PPT were identified. The trial procedures proved feasible, and a sample size for a future definitive RCT was calculated.

**Treatment effect**

No significant effect of group was found on wellbeing according to the WEMWBS as the main outcome measure (Section 8.2.3). The sample size needed to achieve a significant outcome in a future trial, i.e. 668 participants per trial arm, would be disproportionate. The size of the expected gain in wellbeing would be of questionable clinical meaningfulness. However, a significant improvement was found on the BPRS, with a moderate effect size in the ITT analysis (Section 8.2.3) and a slightly stronger effect in the sensitivity analysis (Section 8.2.5). The BPRS is a researcher-rated scale, which in this non-blinded study might be susceptible to detection bias. However, the possibility of bias is to some degree offset by the fact that effects bordering on significance were also found on the patient-rated SDHS scale, measuring depression (Section 8.2.3 and 8.2.5). This may be interpreted as a triangulation to support the positive impact of WELLFOCUS PPT on symptomatology, particularly depression.

The positive effect of WELLFOCUS PPT on depression is a promising finding, potentially pointing towards future uses of the therapy. Standard PPT was developed for people with depressive symptoms, so it is consistent that WELLFOCUS PPT has the potential to improve depressive symptoms in people with psychosis. Comorbid depression is a known challenge in the treatment of people with psychosis as it is associated with poor outcome, with estimates of comorbidity ranging between seven and 80% (Scholes and Martin 2013). A 7.5-year prospective study after hospitalisation
found 40% with a full depressive syndrome diagnosis (Sands and Harrow 1999), and the same prevalence was found in those with at risk states or first episode psychosis (Fusar-Poli et al. 2014). Given the favourable effect of WELLFOCUS PPT on depressive symptoms, it could be a valuable tool for specifically targeting comorbid depression in people with psychosis. Other important fields of further development for WELLFOCUS PPT might be specifically targeting people with dual diagnoses, i.e. psychosis and substance abuse, for whom interventions are being developed and tested but are still rare (Johnson et al. 2007), or further exploring the impact of culture on processes and outcomes. The forgiveness and gratitude components within WELLFOCUS PPT are complex elements which may be susceptible to differing attributions and potentially differential effects depending on participants’ culture and religion. Spiritual beliefs have been shown to be important for people with psychosis in different cultures (Saravanan et al. 2007) and can impact significantly on outcome (Johnson et al. 2012).

Additional analysis showed a limited effect of therapy group on outcome (Section 8.2.4). This implies that effect modification through therapy group was not an issue in our study. Similarly, hardly any effect of age and gender on results was found (Section 8.2.5). This implies that age and gender do not act as important confounders in this study, despite the fact that age significantly predicted attendance. Nevertheless, ideas on wellbeing and strategies to improve wellbeing are likely to differ between young people, e.g. with first episode psychosis, and older people, e.g. with a chronic course of illness. Further specifically optimising WELLFOCUS PPT for these age groups might also be the goal of future research.

At least five explanations might account for the lack of impact on wellbeing. First, WELLFOCUS PPT may not be suitable for increasing wellbeing within a timeframe of 11 weeks. This argument is supported by meta-analytic evidence showing that positive psychology interventions in general are more effective when administered as individual therapy and over relatively longer periods of time (Sin and Lyubomirsky 2009). Second, the WEMWBS may not be sufficiently sensitive to detect change between baseline and follow-up in people with psychosis. One controlled intervention study using the WEMWBS found it to be sensitive to change, with respective participants taken from a waiting list. They can therefore be assumed to have been highly motivated, and most did not suffer from psychosis (Margrove et al. 2012). Third, the concept of wellbeing is complex and there is no agreement in the literature on
what it actually consists of (Schrank et al. 2013a). The particular changes in wellbeing potentially brought about by WELLFOCUS may not be captured by the WEMWBS. By contrast, the Positive psychotherapy Inventory (PPI) is also a measure of wellbeing and it showed significant changes attributable to the intervention. The PPI was specifically developed to measure change following PPT. While this may make it more responsive to change due to a Positive Psychotherapy intervention, it may conversely be a process, rather than an outcome, measure. Fourth, the study design which allowed all participants to receive any non-study care including psychotherapeutic interventions may have diluted the trial’s effect size. Fifth, WELLFOCUS PPT may be ineffective for improving wellbeing in people with psychosis. This explanation is supported by the high sample size necessary to show a significant result on the WEMWBS (Section 8.5.4) and the confidence interval approach which indicates that only small changes in wellbeing of about 0.13 points on the 5-point WEMWBS are likely to be found (Section 8.5.3). On the other hand, the suggestion of ineffectiveness is offset by the conceptual uncertainties surrounding the concept and measurement of wellbeing and by the results of the qualitative process evaluation suggesting that the hypothesised changes due to WELLFOCUS did indeed occur (Section 8.3.2).

**Design challenges**

At least three specific design challenges may have contributed to the non-significant results of the WELLFOCUS Trial. These include access to non-study (routine) care, non-blinding of routine care providers, and lack of assessment of wellbeing confounders. All of these challenges will need to be addressed in a definitive WELLFOCUS RCT, as outlined in Section 9.4.

**Design challenge 1: Non-study (routine) care**

The potential influence of non-study care, i.e. extrinsic services available through routine care pathways, is particularly important in an unblinded trial in which control group participants received TAU. An important consideration when discussing the effectiveness of an intervention study pertains to control group stringency, i.e. the magnitude of impact on the outcome variable that a control condition is designed or expected to have, and control group uniformity. Control group stringency reduces the outcome difference between intervention and control arm, thus decreasing statistical power (Freedland et al. 2011). Hence, using TAU as a low stringency control condition may have led to an increase in the difference between intervention and control arm. At the same time, control-group uniformity may increase between-group differences by
decreasing within-group differences, thus increasing statistical power (Freedland et al. 2011). In the WELLFOCUS Trial the uniformity in the control group was low in that participants were recruited from both in-patient and community settings, and even amongst those recruited from community services access to other routine psychotherapeutic interventions was variable.

In principle, the availability of alternative non-study interventions may influence the delivery and acceptability of the experimental intervention and modify its effects leading to subtle and difficult to detect confounding. For example, if alternative and potentially less burdensome interventions are easily accessible for the same target condition, this may decrease service user motivation to engage in the experimental treatment or adhere to it. At the same time, this situation can enhance the external validity of a study (Freedland et al. 2011). The latter may be true for the WELLFOCUS study. An intervention focussing specifically on wellbeing for people with psychosis did not exist outside WELLFOCUS PPT, so alternative treatments could not have been chosen. Moreover, an ‘add-on’ intervention that has wellbeing as its main target outcome may only be readily implemented in a service environment in which other treatments targeting symptoms, deficits, but also resources, already exist. The effect size of any add-on intervention superimposed on an existing established care package will in general tend to be low (Hart et al. 2007).

**Design challenge 2: Blinding**

Blinding in trials is usually considered in relation to the participants, caregivers, and outcome assessors (Boutron et al. 2007). Lack of blinding, especially in participants and outcome assessors has been empirically shown to produce biased estimates of treatment effects while the blinding of caregivers, e.g. physicians providing routine care, is often neglected in trial reports (Boutron et al. 2008). Non-blinded caregivers can cause post-randomisation confounding and biased outcomes through differential intensification of routine care (Freedland et al. 2011). Differential intensification can occur when participants in the experimental treatment are sensitised to certain issues and talk about these to their routine care providers. Equally, routine care providers who know about a person’s assignment to the control condition and are convinced of the benefits of the experimental treatment may encourage access to additional non-study care, leading to intensification of routine treatment in the control group and thus decreasing the effect size of the intervention.
Blinding participants is often not possible and blinding assessors is difficult to maintain in psychotherapy trials (Section 7.1). Non-blinded assessors, in contrast to non-blinded routine care providers, usually cause exaggerated estimates of treatment effects if they are not in true equipoise about the experimental treatment (Wood et al. 2008).

**Design challenge 3: Wellbeing confounders**
Wellbeing may be influenced by a range of variables and events outside of mental health care. The conceptual work undertaken in the context of this thesis (Schrank et al. 2013a, Schrank et al. 2013b) demonstrates the complexity and diversity of factors and processes that impact on wellbeing. Major confounding factors that have been empirically shown to impact on wellbeing in people with psychosis include medication changes (Karow and Naber 2002), enduring social conditions and short term life events (Yanos and Moos 2007). Theoretically, these influences should be evenly distributed across randomised participants. However, their impact may still differ between groups due to the specific interventions they receive. Hence, while it may neither be feasible not necessary to control for all possible influences on wellbeing, a definitive trial might still aim to measure these known prognostic indicators by systematically assessing the most prevalent influences on wellbeing both in the context of mental health care and beyond (see Section 9.4).

**Objective 1: Piloting the intervention**

**Feasibility and acceptability**
The attendance rate of 54.2% in the present study can be regarded as adequate given the 11-week duration of the group therapy and the moderately symptomatic and long-term service use characteristics of participants. Poor attendance rates (Mueser et al. 2013a) and high drop-out rates (Martin et al. 2006), even in excess of 50%, are a known problem in intervention studies with people with severe mental illness, especially in outpatient settings. Overall, for cognitive behavioural therapies for schizophrenia, systematic review evidence suggests an average attrition of at least 30% (Cormac et al. 2002)

The process evaluation identified reasons for non-attendance suggesting that attendance in a definitive RCT could be increased through specific support, including regular reminders, reassurance and discussing reasons for non-attendance. Therapy completion rates (i.e. attendance of >50% of sessions) was at 55.3% and loss to
follow-up low, pointing towards the reasonable feasibility and acceptability of WELLFOCUS PPT, given that poor compliance rates are a known significant problem in this client group (Tarrier and Wykes 2004). Completer data are difficult to extract from the published literature, especially for psychotherapy studies, and the definition for ‘completer’ differs across trials. For medication studies, non-adherence of around 55% is found for people with psychosis (Chang et al. 2010).

Completion of ongoing tasks ranged between 41.2% and 95.0% between groups, pointing to a good acceptability also of the homework. Homework completion is often not reported in RCTs although the assignment of homework tasks is a common component in many psychotherapeutic interventions, especially CBT. Where homework completion is reported, average ranges in similar client groups differ, with numbers around 50% (Mueser et al. 2008) and as high as 75% (Granholm et al. 2005).

Overall, feasibility and acceptability of WELLFOCUS PPT appears promising. However, a definitive WELLFOCUS RCT will have to include efforts to increase attendance and completion rates. As suggested in the qualitative process evaluation (Section 8.3.1) this might include measures to reduce anxiety and facilitate group bonding at the beginning of the intervention, individualised encouragement to attend despite psychotic symptoms or lack of motivation, and support with transportation to the therapy location.

Validation of the WELLFOCUS Model
Quantitative and qualitative process evaluation showed no obvious breakdown in the proposed intermediate processes of the WELLFOCUS intervention model. However, despite the apparent applicability of the model in terms of change processes, the quantitative outcome evaluation showed no consistent change in the hypothesised outcomes, disconfirming the model. There are at least three possible explanations for the model breakdown at the point of outcome assessment. First, the hypothesised intermediate processes may have been generic enough to apply to change in the context of any psychotherapy, but too generic to specifically apply to changes in wellbeing. Alternative processes may be more relevant to change in response to WELLFOCUS PPT. Second, the measurement of wellbeing and the hypothesised indicators of wellbeing in the WELLFOCUS model may have been inadequate due to conceptual and psychometric shortcomings in the assessment tools (as outlined above). Third, the four areas conceptualised as target areas of change in the model
may have been better construed as outcomes instead. This is supported by the positive feedback on change in the hypothesised target areas in the qualitative process evaluation.

Given the lack of effect of WELLFOCUS PPT on the primary outcome (WEMWBS), the lack of influence of variation in process ratings on variation in outcome is not surprising. No inferential analyses were conducted to test for predictors of variation in process evaluation ratings. This decision was based on two considerations: (i) the exploratory nature of the pilot trial with its small sample size, and (ii) the fact that no \textit{a priori} hypotheses had been developed and hence variables potentially influencing processes have most likely not been measured. A range of reasons may have influenced the experience of processes, which are beyond the scope of this study.

Overall, the model supports change in the target areas and the broad applicability of the intermediate processes, but no effect of WELLFOCUS PPT on the hypothesised outcomes. A modified WELLFOCUS PPT model might consider using the target areas as outcomes indicating improved wellbeing. The individual exercises contained in WELLFOCUS PPT might best be regarded as active ingredients representing the intervention in the model. This would also facilitate a more differentiated evaluation of the value of individual components of WELLFOCUS PPT on outcomes (see further discussion in Section 9.4). More conceptual work will need to be done to propose adequate intermediate processes affecting outcome on top of the generic process components included in the WELLFOCUS model. A speculative amended version of the WELLFOCUS Model is displayed in Figure 9.1.
Some further adaptations to WELLFOCUS PPT were suggested in participant and therapist feedback in order to optimise understanding and maintenance, further optimise the intervention for client group, and optimise therapist involvement (Section 8.3.3). Correspondingly, adaptations of WELLFOCUS PPT were identified in relation to (i) the sessions, (ii) the manual, and (iii) the journal and worksheets.
Changes to the sessions

In general, work in pairs will be changed to all-group exercises, and a more extensive rationale will be provided for each of the exercises to make them more meaningful and relevant to participants. The number of sessions will be increased from 11 to 13.

Session new ‘Introduction’: An additional first session will be included to further explain the therapeutic approach, address how problems will be dealt with, counter anxiety, and bond with other group members.

Session 1 ‘Welcome’: More time will be devoted to explaining positive responding (whilst dropping the role-play) and positive responding will be explicitly encouraged throughout the course of the therapy. The exercise ‘Positive introduction’ will be renamed to “When I am at my best” and repeated three times in the course of the therapy.

Session 2 ‘Savouring’: Emphasis will be taken off savouring food and more time devoted to enjoying other experiences and to transferring the skill into daily life. Savouring of music will be emphasised to facilitate the music savouring exercise at the beginning and end of each session.

Session 3 ‘Good things’: More emphasis will be placed on being concrete, taking exact notice of the good things that happened, and enlisting help and support of friends or family members in collecting items or ideas of good things. Feedback on one good thing that happened last week will be requested from at least one participant in each session throughout the therapy to encourage transfer into daily life.

Session 4 ‘Personal strengths’: The warm-up exercise in this session will be dropped and the identification of strengths encouraged through more general group discussion and discussion of the strengths pictures. More time will be spent discussing the rationale of the strengths focus.

Session 5 ‘Personal strengths activity’: more discussion will be devoted to picking a suitable activity and ensure that it is something participants would not have done anyway.

Session 6 ‘Mid therapy check’: This session so far contained a strengths activity with another person. It will be changed into a repetition session (similar to standard PPT), recapping on everything that has been learned so far, discussing ways of transferring new skills into daily life (i.e. maintenance), and preparing participants for the more difficult topics to be covered in the sessions to come. The ‘Compliments’ exercise will be retained, the ‘When I’m at my best’ exercise will be repeated.
Sessions 7 and 8

‘Forgiveness’: The warm-up exercise and most of the hand-outs will be dropped, more time will be devoted to exploring forgiveness in group discussion, and to picking adequate examples for each person to complete the exercises “Tug of war” and “Forgiveness letter”.

Session 9

‘One door closes, another door opens’: This session will be held before the forgiveness sessions, with more time devoted to discussion and a greater emphasis on how participants have helped others to see the positive side of things in order to view the difficult topic from a different perspective, gain self-confidence, and add a better sense of usefulness to the exercise. The session will be re-named.

Session 10

‘Gratitude’: More time will be devoted to discussion instead of writing the letter.

Session new

‘End therapy check’ This will be a general recap session, including reflecting on the gratitude letter, discussing what participants have put in their good things boxes and discussing participants’ stories of ‘When I am at my best’. Maintenance of gains will also be discussed.

Session 11

‘Celebration’: the separate exercise on positive responding will be dropped from this session.

Changes to the manual

A more detailed therapeutic rationale will be included at the beginning of each session, together with learning goals and an additional brief summary of all exercises and time devoted to them. The example script will be replaced with less patronising instructions. They will contain more meaningful and practically relevant examples, and be easier to deliver in terms of wording. More information and guidance on self-disclosure will be provided.

Changes to the journal and worksheets

The journal will be reduced in size and weight, contain a pen and potentially a calendar. The worksheets will be written with bigger font size and less words avoiding lengthy and potentially difficult to understand expressions. All pictures will be revisited to maximise relevance and ensure copyright requirements are met.
**Objective 2: Piloting the trial processes**

The overall consent rate of 40.2% can be regarded as acceptable given the target group of people with psychosis. Consent rates reported in other RCTs with comparable client groups range widely, with examples of 32.6% (Jackson et al. 2008), 35.4% (Rathod et al. 2013), and 61.8% (Staring et al. 2013), but also as high as 68% (McGorry et al. 2002). The randomisation process was also well accepted and successful overall. Groups differed significantly on just one variable at baseline, which is to be expected among more than 20 tests given the alpha level of 0.95. Waiting times between referral and the start of therapy varied widely between individuals. However, this appeared not to affect acceptability as waiting times were unrelated to completer status. Overall, these results suggest that the trial processes were feasible and acceptable to both clients and therapists.

The processes in a definitive RCT will differ slightly from this pilot study. Most importantly, a definitive RCT will employ a more representative, e.g. random, sampling strategy which may decrease the consent rate. The inclusion of an active control group or restrictions to non-study care in the comparison group may also negatively impact on consent rates.

Recruitment through care coordinators may need to involve a structured researcher led screening of the inclusion criteria for all service users on their case load. This will minimise care coordinators’ subjective judgement of participant suitability but also potentially further reduce the recruitment pool. Inclusion criteria are likely to include specific research diagnoses, e.g. in the schizophrenia and bipolar spectrum, a verification of cognitive functioning, and a more formal assessment of English language skills.

**Objective 3: Piloting the evaluation strategy**

The outcome evaluation strategy proved acceptable and feasible, and correlations between baseline and follow-up results can inform sample size calculations not only in a future definitive WELLFOCUS RCT but also other studies conducted with similar client groups.

The choice of primary outcome measure for a definitive WELLFOCUS Trial remains difficult given the unique focus of WELLFOCUS PPT on improving wellbeing in participants with psychosis. Currently, no gold standard measure of wellbeing exists, and most wellbeing measures have no published comprehensive psychometric
properties. Especially, evidence on sensitivity to change is lacking for people with psychosis (Section 2.5). Equally, existing outcome measures may not be able to capture relevant outcome domains of improved wellbeing, specifically in people with psychosis linked to WELLFOCUS PPT. The problem of choosing adequate outcome measures has been noted before for CBT for psychosis, leading to the development of a novel measurement tool which more strongly reflected the aims of CBT for psychosis and the priorities of the service users concerned (Greenwood et al. 2010). The development of a new measurement tool reflecting the concept of wellbeing specifically in people with psychosis and relevant wellbeing gains connected with WELLFOCUS PPT may also be a way forward for positive psychotherapy research in psychosis. Developing a new measure would involve a cyclical process of additional qualitative research to define outcomes associated with improvements in wellbeing using interviews and focus groups, consensus methods such as Delphi Consultation to identify consensus on an item pool and item wording and the adaptation thereof, piloting and adaptation of the constructed measure, and a larger sample evaluation of the adapted measure including convergent and divergent validity, test-retest reliability, factor analysis and sensitivity to change.

The present pilot study suggests that symptoms associated with psychosis, as measured by the BPRS, would be a promising main outcome, requiring 84 participants in each of two trial arms to evaluate WELLFOCUS PPT. However, in a definitive RCT with blinded assessors and a more stringent control group, differences between the groups may decrease and a higher sample size may also be required for this outcome. A more comprehensive assessment of depression, and potentially of positive affect, may also prove valuable in a definitive WELLFOCUS Trial. This is relevant for two reasons. First, it has been empirically shown that depression and positive affect (which can also be considered as affective domains of wellbeing, as outlined in Section 2.3) have a particularly strong influence on cognitive aspects of wellbeing, such as life satisfaction (Mankiewicz et al. 2013). Second, WELLFOCUS PPT appears to be a promising intervention to target these affective domains of wellbeing. A number of validated assessment tools exist for the measurement of depression and positive affect (Section 2.3).

The confidence interval approach confirmed the appropriateness of the BPRS for measuring symptomatology and the SDHS for measuring depression in the context of WELLFOCUS. Estimates for differences between groups at follow-up were -4.00 (CI -
6.68 to -1.32) for the BPRS and -0.21 (CI -0.45 to 0.03) for the SDHS. The BPRS covers a range of sum scores between 18 and 126 and the SDHS mean scores are between 1 and 4. Participants in our intervention group were ‘mildly ill’ with average BPRS scores of 30.7 (Leucht et al. 2005) at intake. This means a reduction of four points on the BPRS corresponds to a 13% improvement. Clinical studies often use a cut-off to define response on the BPRS with the smallest used cut-off at 20%. This equals a ‘minimal improvement’ according to the raters’ clinical impression (Leucht et al. 2005). Hence, an improvement of 13% may not be detectable clinically. An improvement of -0.21 on the SDHS represents a 9.2% reduction in depressive symptoms given the mean baseline SDHS scores in the intervention group of 2.3. Guidelines for what constitutes clinically relevant improvement do not exist for the SDHS and change scores for depression (especially controlled for baseline depression scores) are often not reported in psychotherapy studies involving people with psychosis. Examples that can be found in the literature include a 16% improvement on the Montgomery Asberg Depression Rating Scale (Turkington et al. 2002), or a 7% improvement on the Calgary Depression Rating Scale for Schizophrenia (Klingberg et al. 2011) following CBT for psychosis.

Fidelity assessment proved feasible and sensitive to deviations from fidelity parameters. Overall fidelity was high, indicating that provider training, treatment delivery and treatment receipt were reliably delivered. In a definitive RCT, fidelity will also have to be assessed in the control group, especially if an active control group is used, in order to assess contamination.

The quantitative process evaluation strategy used in the WELLFOCUS study could be further improved for a definitive trial. The shortcomings of the current assessment were (i) the different rating scales used for each assessed item which required complex statistical procedures to generate overall scores or scores that compared to the participant rated process evaluation results, (ii) the narrow range of the applied rating scales (i.e. 0-2 or 0-3), so floor or ceiling effects may have restricted the capacity of the assessment to capture variation between individuals, (iii) the high burden of rating after each session for researchers, and (iv) the high correlation of the researcher rated process evaluation with attendance at a level of \( r=0.99 \). Together, this casts doubt on the usefulness of the researcher rated process evaluation. Participant rated process evaluation also seemed to be more sensitive to differences between therapy groups and may therefore be the preferred option for a definitive
RCT. One shortcoming of the participant rated process evaluation was that it was undertaken retrospectively at the follow-up assessment. This means that the predictive power of the participant rated process evaluation for outcomes may in part be due to a measurement effect, since measures taken close together in time are usually more highly correlated than measures taken far apart in time (Littell et al. 2000). This could be addressed by administering a participant-rated process evaluation questionnaire immediately following each individual session.

Comparing WELLFOCUS PPT with other interventions adapted for psychosis

The modification of standard PPT into WELLFOCUS PPT can be compared to the adaptation and application of other forms of psychotherapy for people with psychosis. Prominent examples include CBT for psychosis, which has attracted a wealth of research in the last decades, or mindfulness based therapy for psychosis, which is a more recent development. Parallel points of development can be identified for those therapies and WELLFOCUS PPT, as outlined now.

*Cognitive behavioural therapy for psychosis*

CBT was originally developed for the treatment of depression and anxiety in the 1960s and 70s mainly by Aaron Beck and Albert Ellis and successfully adapted for a wide range of conditions (Gaudiano 2005). Beck reported the successful treatment of a patient with psychosis in the 1950s (Beck 1952) but there were no scientifically rigorous reports on psychotherapeutic treatment in this client group. An assumption that patients who experience delusions and hallucinations are not responsive to talking therapies prevailed until the late 20th century, when the first studies applying CBT to people with psychosis emerged (Mueser et al 2013b). Up until the time it was targeted towards people with psychosis, ‘original’ CBT had continued to evolve from focusing on behaviour and cognitions to also including more psychodynamic ideas. This led to the development of several models of CBT called ‘first generation’, second’ generation’, or ‘meta-models’ of CBT (Addington and Gleeson 2005). The wealth of pre-existing research may be one of the reasons why CBT protocols applied to people with psychosis did not use one specific model of CBT and included a range of different elements in their treatment packages (Tai and Turkington 2009). In terms of quality, initial studies were often uncontrolled or compared CBT to TAU, while later studies used active comparators (Bechdolf et al. 2010, Durham et al. 2003, Bechdolf et al. 2004) and investigated differences in the effectiveness of individual or group CBT for people at specific illness stages, e.g. in early intervention (Lewis et al. 2002,
Tarrier et al. 2004), older people (Granholm et al. 2002), acute psychosis (Drury et al. 1996), with comorbid substance abuse (Haddock et al. 2003), or specifically for relapse prevention (Gumley et al. 2003). Today, the application of CBT to people with psychosis is recommended at any stage of the illness by the National Institute of Clinical Excellence (NICE 2009).

Despite the advanced state of research in CBT for psychosis, a number of open questions and research goals have been identified (Gaudiano 2005, Velligan 2009, Morrison 2009): For example, future research may establish which CBT techniques are most effective for improving specific outcome domains, which individual patient characteristics predict outcome, which mechanisms of change account for improvement in specific outcomes, how CBT might be incorporated in other evidence based treatment approaches, and how specific common comorbid conditions such as mood and anxiety disorders, substance abuse, or past trauma could be addressed most effectively. Moreover, since many patients still do not respond satisfactorily to CBT, even in addition to medication and other multi-professional treatment input, the development of further novel therapy approaches has been called for (Mueser et al. 2013b, Morrison et al. 2014).

Mindfulness based therapy for psychosis

A similar development can be observed for mindfulness based therapies. Mindfulness originated from Buddhist meditation techniques and initially evolved into therapeutic interventions for chronic pain (Reiner et al. 2013) and later for mood and anxiety disorders (Roemer et al. 2013, Hofmann et al. 2010), and a range of other conditions including psychosis (Shonin et al. 2014). Early studies on the application of mindfulness techniques in people with psychosis included a series of case reports (Shonin et al. 2014), followed by a small uncontrolled feasibility study of group mindfulness therapy for psychosis (Chadwick et al. 2005), and later RCTs using waiting list or TAU controls, and finally active control groups with longer follow-up periods and investigating effectiveness for specific symptom domains, especially negative and affective symptoms (Khoury et al. 2013). Identified future research implications also reflect those identified for CBT in psychosis, including long term outcomes, and potential moderators and mediators of outcome. Identified methodological challenges include more attention to non-specific treatment effects and better concepts and operational definitions of mindfulness (Khoury et al. 2013).
Parallels with WELLFOCUS PPT

Both the developmental trajectory and the future research goals of CBT and mindfulness therapies compare with WELLFOCUS PPT. Specifically, the WELLFOCUS Trial represents an early stage in the generation of evidence, comparable to early studies on CBT or mindfulness for psychosis. Future research on WELLFOCUS PPT will need to include larger trials with active comparators; more narrowly defined target groups, such as early psychosis, older adults, acute versus chronic psychosis (Gaudiano 2005), or comorbid conditions, such as the important challenge of substance abuse (Phillips and Johnson 2003); the exploration of mechanism and predictors of effectiveness; and further attention to conceptual and measurement issues. Future research implications for WELLFOCUS PPT are outlined in detail in Section 9.5.

9.3 Strengths

Adapting PPT for people with psychosis shares some commonalities but also differs from the development of CBT for psychosis in certain respects. In contrast to CBT when targeted towards psychosis, research on ‘original’ PPT is still in its infancy. Hence, there was only limited literature on treatment models and theories of effectiveness. Consequently, the adaptation of PPT had to take a highly comprehensive approach, starting with a systematic review and qualitative research in order to develop theory and to create an evidence-based treatment model prior to the actual adaptation of PPT. No equally comprehensive research programme has been undertaken in the initial stages of adapting CBT for psychosis.

The careful development of theory is a particular strength of this thesis. It integrates different forms of evidence derived from multiple research techniques, and could hence be positioned as mixed methods research. Mixed methods research has evolved in recent decades as the “third methodological movement” (Denzin and Lincoln 2011) (p.285) to overcome the paradigmatic split between quantitative and qualitative research paradigms and instead integrate multiple methods (Feilzer 2010). A whole new epistemology and typology of mixed methods research has been established (Johnson and Onwuegbuzie 2004), which is beyond the scope of this thesis to describe in detail. However, the pragmatic and research question-driven combination of methodological approaches is the hallmark of this approach to research.
WELLFOCUS PPT was developed by first understanding the intervention and how it might work in the target population (instead of just applying a given intervention to a new client group), with the aim of increasing its clinical relevance. Substantive changes were made to standard PPT to develop a version applicable to people with psychosis, including changing elements, cutting existing elements, and adding new elements, as described in Section 9.2.

The pilot RCT evaluating the newly developed intervention carefully integrates process and outcome evaluation, by applying the established MRC framework for the development and evaluation of complex interventions (Craig et al. 2008), guidelines for conducting pilot studies (Lancaster et al. 2004, Thabane et al. 2010), and an established framework for fidelity and process evaluation (Bellg et al. 2004), with the aim of maximising the gain in relevant evidence.

### 9.4 Limitations

This thesis has at least six limitations. These pertain to challenges surrounding the definition of wellbeing and the methods for conducting the pilot RCT.

First, the lack of a pre-existing consensus definition of wellbeing, as confirmed by the systematic review (Chapter 4), required the development of a definition of wellbeing applicable to the client group of people with psychosis (i.e. enhanced sense of self, see section 5.2). The approach chosen in this thesis included a narrative synthesis based on a systematic review (Chapter 4) and a qualitative study using semi-structured interviews with people with psychosis (Chapter 5). Other researchers may have chosen different methodological approaches, such as consensus methods.

Second, the static framework of wellbeing was created by synthesising wellbeing concepts underlying the assessment tools applied in the studies included in the systematic review (Chapter 5). Given the inclusion criteria for the systematic review, i.e. intervention studies only, the list of captured assessment tools was not exhaustive. Creating a meta-framework of wellbeing from all existing wellbeing measures would have required a different review question and search strategy.

Third, the lack of definition for wellbeing may also have limited the usefulness of the results of the qualitative research stage to create the dynamic framework of wellbeing. Interviewees were not guided towards a specific definition of wellbeing. Hence, their accounts on the concept and the involved processes spanned a wide range of issues,
according to subjective ideas and perceptions. This led to the development of a dynamic framework of wellbeing which spans a wide range of areas covering basically any aspects of life that might be important, which may limit the informativeness of the framework. However, results may also indicate that the concept of wellbeing is emerging as one that may span anything of value to people. More in-depth qualitative as well as quantitative research may add to developing a comprehensive as well as a practically useful concept of wellbeing.

Fourth, since the WELLFOCUS Trial was the first to test a newly developed intervention it is positioned as a pilot trial according to the MRC framework for the development and evaluation of complex interventions (Craig et al. 2008). Methodological limitations include the non-random sampling, the use of clinical instead of research diagnoses, unblinded outcome evaluation, the use of TAU instead of an active comparison group, and non-monitoring of other psychological interventions participants may have received during the study period. However, this study used methods derived from guidelines for design choices in pilot studies (Thabane et al. 2010, Lancaster et al. 2004). In addition, a number of approaches were used to minimise bias, as described in Section 7.10.3. While the clinician-identified convenience sample may have led to selection bias, internal validity was protected through independent random allocation. The ITT approach reduced the impact of selective attrition and the use of standardised assessments minimised bias in the outcome. Also, treatment outcomes were assessed at follow-up by researchers who were not involved in the participants’ WELLFOCUS group, nor, where possible, in their baseline assessment. Since the aim of the intervention is to augment existing treatment, TAU is an appropriate comparator. Existing mental health services already include access to a range of psychological interventions (not currently including PPT), which reduces the need to control for non-specific effects such as therapist attention.

Fifth, the use of broad clinical diagnostic criteria, i.e. psychosis, and convenience sampling according to care coordinators’ judgement of participants’ suitability for a group psychotherapy intervention led to a sample with overall only mild illness symptoms at intake. Delusions, hallucinations, thought disorder and also hypomanic states were clinically observed in participants throughout the course of the therapy, but not assessed at any other point than baseline and follow-up. Potential interference of more pronounced symptoms with therapy content or attendance rates was not systematically evaluated. Overall, WELLFOCUS PPT seemed to be generally feasible.
for people at any stage of illness but a future RCT will have to specifically address the influence of symptoms on therapy and the effectiveness of the intervention with service users in specific diagnostic categories, such as schizophrenia, schizoaffective disorder and bipolar affective disorder.

Sixth, another issue arising during the pilot RCT was the higher than expected referral and recruitment rate. This led to an over-recruitment in comparison to the planned target of 80 participants. Over-recruitment into a pilot study may be considered ethically questionable. However, given the lack of adverse effects, the overwhelmingly positive feedback from initial therapy groups, and the unexpectedly high interest of patients in WELLFOCUS PPT, the likelihood of negative effects due to WELLFOCUS PPT was deemed extremely small, and outweighed by the equally ethically problematic approach of withdrawing the initial offer of therapy made through care coordinators. Consequently, all available participants were randomised.

9.5 Conclusions and implications

This thesis has demonstrated the applicability, acceptability and potential to benefit from a new psychological intervention oriented towards wellbeing. The application of findings from Positive Psychology to people with a psychosis diagnosis is supported. The results indicate that future efforts to find new ways of supporting greater wellbeing in psychosis are worthwhile.

**Scientific implications**

This thesis has advanced the understanding of the concept of wellbeing and the processes involved in improving wellbeing. However, as indicated by the results and limitations of the systematic review and qualitative study, more research is needed to develop a sound, comprehensive, and practically applicable evidence based concept of wellbeing for people with psychosis. Based on such an improved understanding of wellbeing, future research might involve the rigorous development and evaluation of a valid and psychometrically sound measurement tool for wellbeing in this client group, as well as hypothesis based prospective studies to investigate wellbeing processes. Important research questions include the identification of how wellbeing unfolds over time in people with psychosis, what influences wellbeing prospectively, or what might be the neurobiological correlates of wellbeing. These questions might be approached using observational prospective studies, e.g. with objective data collection and participant diary. Such prospectively gathered data will produce a higher level of
evidence than was the case for the retrospective data on influences on wellbeing gathered in the qualitative sub-study of this thesis.

The results of the pilot RCT suggest that WELLFOCUS PPT may be a promising intervention to reduce overall symptom severity and depression in people with psychosis. Future research might involve a definitive RCT evaluation of WELLFOCUS PPT to establish its effectiveness, and evaluation by a different research group. Subsequent research stages might also investigate the effectiveness of WELLFOCUS PPT on specific diagnostic sub-groups, such as bipolar mania or bipolar depression, and clinical sub-populations such as those with dual diagnosis, first episode psychosis, older adults, or acute versus chronic psychosis. Larger studies might also establish the effectiveness of individual WELLFOCUS PPT exercises for the improvement of specific psychotic symptom domains, such as positive and negative symptoms, affective symptoms, or thought disorder. Further important research questions pertain to the establishment of mechanisms, moderators and mediators of effectiveness. Candidate moderators include severity of symptoms in specific domains, e.g. positive symptoms, thought disorder, or mania; socio-demographic background variables, e.g. housing problems, social isolation, or other long term disadvantages; insight into illness or cultural background and spiritual beliefs. Hypothesised moderators will have to be measured at baseline to investigate their influence on differential responsiveness to the intervention.

Characteristics of a future definitive trial
Methodological implications for a future definitive RCT include attention to at least nine factors, constituting an improvement of the methodological approach used in the present pilot study.
1. Measurement: measurement strategies for wellbeing will need to be carefully considered to choose an instrument that is valid, reliable, and sensitive to change in the given population.
2. Inclusion criteria: more narrow inclusion criteria specifying specific clinical sub-populations will need to be applied.
3. Sampling: To minimise selection bias, a random sampling strategy will have to be applied, for example including all people on the case load of care coordinators in participating services as the population to be randomly sampled from, with inclusion criteria verified by research workers instead of care coordinators.
4. Blinding: assessment staff will need to be blind to treatment allocation to prevent bias in follow-up data collection, routine care providers will need to be blinded to allocation status to prevent differential intensification of routine treatment.

5. Control group: As outlined in detail in Section 7.8.1, the choice of control group is complex but important in psychotherapy trials. Different types of control conditions can have a significantly different effect on the outcomes under investigation. In a definitive RCT an active, or at least a more restricted and monitored, control condition will have to assess treatment fidelity, importantly including contamination in the control group. It will have to account for clinician selection and allegiance effects, to reduce the extent to which highly selected, skilled and enthusiastic therapists in the experimental arm have an excessive ‘non-specific’ positive effect on outcome, and it will adequately control for attention effects, whilst taking the implications of different control groups on other ‘non-specific’ factors such as expectancy (as tied to credibility) into consideration.

6. Non-study (routine) care: certain forms of non-treatment care or of changes in the receipt of non-treatment care, e.g. other psychotherapeutic interventions or medication, may be restricted for study participants. Receipt of non-study care will have to be meticulously assessed in all trial arms, to establish not only the quantity but also the quality of non-study care, e.g. using checklists based on clinical treatment guidelines.

7. Confounders: Potential alternative predictors for therapy outcomes or for the experience of therapy processes, such as socio-demographic characteristics, cultural background, or life events may be assessed at baseline to establish their moderating effects.

8. Process assessment: more complex and sophisticated processes than in the present study might be investigated in a definitive RCT. The processes involved in increasing wellbeing through WELLFOCUS PPT will first have to be established in further qualitative and prospective research. Process evaluation will also take into account treatment dose, intensity, and a refined definition of the active ingredients of WELLFOCUS PPT as well as possible confounders for wellbeing.

9. Economic evaluation: A definitive RCT will have to include an economic evaluation.
Clinical implications

Results showed that WELLFOCUS PPT was well received by patients and therapists, recruitment rates were unexpectedly high and feedback overwhelmingly positive. Together this indicates that psychotherapeutic interventions focusing on strengths, resources and positive experiences are in demand in routine services for people with psychosis. Given the sound development process for the new intervention, clinicians might consider using positive techniques tested in WELLFOCUS PPT in their work, for example to increase group coherence, atmosphere, or working alliance, even before definitive evidence on the effectiveness of WELLFOCUS PPT for the treatment of specific symptoms is available. Particularly well received techniques that can be included in any therapeutic context were ‘Savouring’, including the mindful savouring of music at the beginning and end of each session, and ‘Identifying personal strengths’. Long-term goals might be the introduction of wellbeing workers, e.g. in primary care settings, or wellbeing therapists within specialist mental health teams.

Overall, further development of research and practice to support wellbeing in psychosis is warranted. For people with psychosis the goal of experiencing an enhanced sense of self can be informed by the work presented in this thesis.


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Appendices

Appendix 1: Publication corresponding with Chapter 2 not included in the thesis


Practice points

- Incorporating research on well-being into clinical practice has the potential to improve mental health care
- Using a combination of approaches to measure components of well-being and mental health together with or in addition to scales capturing multidimensional concepts of well-being, is recommended for clinical practise
- The Complete State Model of Mental Health, which captures both mental health and mental ill-health and allows the consideration of well-being despite the presence of mental illness, is recommended as a framework for clinical practice
- Elements of the ‘Good Life’ approach to well-being have the potential to be included in clinical practice as they conform with the transcendent principle of personhood and allow for varied and everyday approaches to increase well-being
- A range of promising interventions exist that target components of well-being, such as self-worth, meaning or hope
- Positive psychology interventions combining a range of resource oriented exercises appear to be promising to improve well-being. Their application to people with mental illness, particularly severe, will need to be established in further research.
Abstract/Summary

The concept of well-being has not been well defined or reliably measured in academic research. This article identifies four academic strands of well-being conceptualisation and measurement (economic, medical, psychological, and integrative) and shows how well-being has shifted from being conceived as a collectivist concept with objective measures, to being conceived in individualistic terms, with subjective measures. Given its clinical relevance the main emphasis is on subjective well-being. While well-being has become a key concept in mental health, the article also discusses some limitations to its use in practice and proposes considerations for future research. Key issues are a consensus definition of well-being in people with mental illness, and empirical studies on the measurement of well-being and its determinants. Future research might be based on the ‘Good Life’ approach, the Complete State Model of Mental Health, or the academic field of Positive Psychology.

Introduction

Well-being has been a topical policy focus in recent years and has attracted research interest across health conditions. An explicit description of the concept of well-being is often absent in research [1]. This article provides an overview on the various concepts of well-being in the literature and their related measurement tools, with a specific reference to mental health. In examining the definitions of well-being, we identify four academic strands of well-being research:

*Economic Strand:* grounded in economic research, well-being is framed in terms of national wealth, social determinants, development and general quality of life.

*Medical Strand:* grounded in medical research, well-being is framed in relation to disorder and illness.

*Psychological Strand:* Grounded in psychological research, well-being is framed in terms of subjective and mental concepts.

*Integrative Strand:* informed by economic, medical, and psychological phases, with a distinct focus on positive psychology and recovery research.

The paper discusses each phase, with particular focus on the birth of the psychological conception and its evolution into the contemporary, integrative phase.
The primary focus is to show how well-being has shifted from being conceived as a collectivist concept with objective measures, to being conceived as an individualistic concept with subjective measures. This transition was instrumental in well-being becoming a key concept in mental health.

**From the economic phase to the medical phase**

In the economic strand, well-being was initially conceived of primarily in collectivist terms. Measuring and comparing the well-being of populations (rather than individuals) was first undertaken by economists in the early 20th century. Initially, financial indicators of well-being such as Gross National Product (GNP) were used to measure and compare. As these failed to discriminate between countries of similar developmental status, alternative economic indices were proposed to estimate societal functioning [2]. These composite measures further increased the validity of well-being estimates. Today, they are known as “Quality of Life” measures. First, they included purely objective measures, such as mortality, nutrition, literacy, clean water supply, or education [3]. Later ‘subjective’ indicators, such as affect, well-being, or life satisfaction were added to capture how people actually feel about their lives [4]. Composite measures of population well-being are still developed today. For example, the UK Office for National Statistics has developed a new assessment of population well-being, including subjective domains such as spirituality, personal and cultural activities, political participation, or life satisfaction in addition to environmental and sustainability issues and UK economic performance [5].

Inclusion of population level health indicators, e.g. mortality, into composite measures evolving from economic research signifies the emergence of the medical strand to well-being research. The addition of subjective measures, e.g. life satisfaction, signifies the emergence of the psychological strand to well-being research. Medical research also marks a shift in that it emphasises individual health status in understanding well-being. Health research is another major application of the concept of quality of life, in this context called “Health Related Quality of Life” (HRQoL).

HRQoL has attracted substantial research since its introduction, as well as criticism for its lack of uniformity and clarity. The terms ‘health related quality of life’, ‘quality of life’ and ‘well-being’ are often used interchangeably, and few articles claiming to measure HRQoL provide a definition or identify constituent domains [6]. Conceptualisations and measures of HRQoL can be described according to a number of defining features, e.g. generic versus disease specific, or objective versus...
subjective. Individual measurement tools often cover widely different dimensions, including access to resources and opportunities, environmental factors, social relationships, employment, leisure activities, sex life, mobility, or satisfaction with social domains. The unifying feature of HRQoL concepts is their focus on illness symptoms and functioning based on the assumption that illness and disability inhibits full well-being [7].

While physical health symptoms and functioning are major domains within HRQoL, measurement tools also often use the terms well-being and mental health (i.e. the absence of mental illness symptoms) interchangeably [8]. Examples of generic HRQoL measures with a mental health or well-being sub-scale include the World Health Organization Quality of Life (WHOQOL) questionnaires with their domain on ‘psychological health’ [9], the European Quality of Life-5 Dimensions questionnaire (EQ-5D) with its ‘anxiety and depression’ domain [10], or the Short Form (SF) measures, with their ‘emotional well-being’ domain assessing feeling happy, sad, depressed, or anxious [11]. Other scales use a more elaborate conceptual foundation grounded in and overlapping with psychological conceptions of well-being. For example, the Lancashire Quality of Life Profile [12] and the Manchester Short Assessment of Quality of Life [13] base their well-being domain on concepts of affect balance, life satisfaction and happiness.

One issue in measuring HRQoL in people with mental disorders is the potential distortion of subjective assessments due to ‘psychopathological fallacies’, most prominently the ‘affective fallacy’ which indicates that the momentary affective state can influence people’s judgement about their overall life [14]. This is most problematic in case HRQoL measures which contain ‘emotional’ items relating to feelings of depression and anxiety, as is the case e.g. in the Quality of Life in Depression Scale [15]. Quantitative results support the ‘affective fallacy’ as depressive symptoms have been shown to have an independent and significantly negative effect on subjective ratings of HRQoL [16].

A second issue is concerns about the reliability of subjective assessment in people with psychiatric disorders. This concern led to the inclusion of supposedly objective assessment methods, derived from clinicians or family members [14]. However, subjective assessment has become more accepted as people with severe mental illness were shown to reliably and consistently complete self-rating questionnaires [17]. Moreover, the views of clinicians and family members may be biased, and

Appendices
service users’ subjective position is argued to be no less true in case it diverges from an outsider. In fact, ‘insider’ and ‘outsider’ perspectives have been shown to differ due to differing values placed on contextual factors and a tendency towards a negative bias from the outsider perspective [18]. This supports the meaningfulness of the subjective assessment of well-being. While in HRQoL subjective and objective measures still coexist, the psychological approach has completely shifted to subjective assessment [19,20,21].

The emergence of the psychological phase
Psychological research has created specific conceptualisations and measures to capture well-being in its own right without embedding it within other constructs such as national development or HRQoL.

As with HRQoL, a review on psychological concepts of well-being criticised frequently missing or ambiguous definitions and the interchangeable use of similar terms [22]. Distinctive features of the psychological approach include its focus on subjective experience and personal feelings, and on positive mental health and functioning, e.g. positive affect, life satisfaction, autonomy, competence or personal growth [19,20,21]. Moreover, specific well-being concepts allow for peak experiences (e.g. peak positive affect) or for the temporary cessation of affective experience during flow [23]. Such specific states of well-being may bring symptomatic relief which will not be captured in measures of HRQoL.

Differences between measures of HRQoL and psychological well-being are empirically confirmed by their only moderate statistical correlations. Factor analysis including twelve scales assessing HRQoL and seven psychological well-being scales showed the two concepts to generally load on separate factors. Correlations between these scales ranged between 0.05 and 0.63, but mostly around 0.2 to 0.4 [24].

Despite broad agreement that well-being is a subjective condition in which positive feelings dominate, there is disagreement over more detailed ingredients of well-being in the psychological approach. Diverging views are often grouped under two broad perspectives: hedonic and eudaimonic. In this context *hedonism* usually refers to maximising pleasure and happiness while reducing pain. The *eudaimonic* perspective maintains that not all desires yield well-being when achieved, even though they might produce pleasure. Instead well-being means to live in accordance with one’s true self and derives from personal growth and self-actualisation, from actively contributing,
holding virtue and doing what is right. Happiness may be a pleasant result of this way of living but not its core [19,25].

Another organising principle for psychological well-being concepts is the distinction between the absence of mental illness symptoms and the presence of positive mental health, e.g. framed as positive emotion. This is reflected in an increasing focus on positively framed items in well-being questionnaires.

One rationale for including positively framed variables (e.g. “I have felt cheerful and in good spirits”, “I woke up feeling fresh and rested”) into measurement tools was the observation that a substantial proportion of people in the general population rarely or never report occurrences of psychological distress symptoms [26]. For example, the USA national comorbidity survey found a proportion of 14.9% of people from 26 samples worldwide to qualify for the diagnosis of a mental disorder [27]. This introduces a ceiling effect [8], i.e. a zero score on a depression scale indicates the absence of depression but not the presence of happiness [28]. Including characteristics of psychological well-being (e.g. zest, interest in and enjoyment of life) increases measurement precision and distinguishes among persons who receive perfect scores on measures of psychological distress [26]. An example of a scale covering both ends of a continuum is the Depression-Happiness-Scale [28,29]. The WHO-5 goes one step further. It contains only positive items and assesses emotional well-being. However, although framed positively the WHO-5 still covers core dimensions of depression and proved to be a sensitive tool for screening for depression and suicide risk [30,31]. This may indicate that simply rewording negative to positive items may not be sufficient to meaningfully capture well-being.

The complex interrelations between the mental health domain in HRQoL and assessment tools designated to specifically measure mental health or well-being are exemplified by the RAND health survey. The original survey included the 38-item Mental Health Inventory (MHI-38) to assess mental health [26]. The MHI-38 had assimilated 15 questions from Dupuy’s General Well-being Index [19,32]. Later, the MHI-38 was condensed into the 5-item MHI-5, which was in turn used as the mental health sub-scale in the ‘Short Form’ HRQoL measures (e.g. SF-36 and SF-20) [33,34]. In addition, from the same item pool items were adapted into the WHO-5, which aims to assess positive mental well-being [8,19]. These measurement overlaps show the gradual development from purely deficit-focused HRQoL measures to measures of positive well-being.
Measuring subjectivity in the psychological strand

Despite their contrasts, the hedonic and eudaimonic views are not independent but overlap conceptually and correlate with each other with varying magnitude [19,25]. The same issue of contrasting but overlapping dimensions also applies to a view of well-being as lack of mental illness versus positive mental well-being, or positive versus negative affect [35]. Hence, measurement tools for well-being may be better described according to their focus on affective, cognitive and multidimensional components.

Affective measures

Assessment tools that conceptualise well-being in terms of affect usually use the term affect to refer to mood states or feelings, without acknowledging the psychological distinctions between affect, emotion and feelings. These scales assume that well-being is the degree to which positive feelings outweigh negative feelings. They measure positive and negative feelings either as two distinct dimensions resulting in separate scores or in one overall ‘balance score’. Prominent examples are the Positive and Negative Affect Scale (PANAS) [36], Bradburn’s Affect Balance Scale (ABS) [25], the Affectometer [37] or the Everyday Feeling Questionnaire [38]. The evident overlap between affective well-being measures and measures of psychiatric symptoms is empirically supported by high correlations especially with depression [29].

Cognitive measures

Affective and cognitive measurement strategies overlap. An example for the intersection between emotional and cognitive understandings of well-being is Diener’s concept of ‘subjective wellbeing’ and the corresponding Satisfaction With Life Scale [39] which assesses positive affect and subjective life satisfaction. Similarly, the Oxford Happiness Inventory defines happiness as a combination of positive affect or joy, satisfaction, and the absence of distress and negative feeling [40].

Purely cognitive measures of well-being include single item questionnaires asking one question such as “How satisfied are you with your life overall?” or “Taking everything into consideration, how would you say you are today?”[19]. This requires respondents to reflect on their overall state of life including all individually relevant domains [41]. As with HRQoL, the ‘affective fallacy’ caveat applies to global cognitive ratings, as they may be influenced by momentary affective states [42]. At the same time global ratings are thought to better reflect subjective valuation since different areas of life may be
valued differently by individuals [43,44].

Global cognitive measures of well-being have been widely applied and inspired the theory of ‘subjective well-being homeostasis’. This theory is based on the finding that mean population values of overall life satisfaction typically vary only within a narrow range. On a scale from 0 to 100, people in Western countries answer the question for overall life satisfaction roughly around 75, in non-Western countries the average lies around 70 [35]. The theory of subjective wellbeing homeostasis is comparable to the homeostatic regulation of body functions. It proposes that subjective well-being is maintained within narrow margins (a ‘set point’) by a set of psychological devices, e.g. cognitive bias, personality factors, and adaptation [46,47,48]. Hence, people maintaining a normally functioning homeostatic system show little fluctuations in well-being as a consequence of normal variations in their living conditions. Only highly unusual events cause the level of global subjective well-being to change temporarily, but it will return to its previous level over time, e.g. the subjective happiness of both lottery winners and paralyzed accident victims soon returns to previous levels [47].

The conclusions that may be drawn for the measurement of well-being in general are that the classic “life as a whole” question is useful as an estimate of the personal set-point of well-being, and is unlikely to change as a result of a therapeutic intervention [49].

**Multidimensional measures**

Multidimensional well-being concepts and their corresponding measures include widely varying psychological dimensions apart from affective and cognitive aspects. Even though multidimensional well-being concepts are most comprehensive, none of them covers all potential well-being dimensions. No single concept can be regarded generally superior to others as their utility strongly depends on the target group to which they are applied.

Ryff’s (1989) multidimensional concept of ‘psychological well-being’ and corresponding Scale of Psychological Well-being (SPWB) captures positive functioning with a focus on life span development, individuation, maturity and self-actualisation [44,50]. The scale’s unstable factor structure has attracted criticism but the particularly comprehensive concept is still used today and informs other conceptualisations of well-being. Likewise, the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) covers a comprehensive understanding of well-being including affective-emotional aspects, cognitive-evaluative dimensions and psychological
functioning [51]. It builds on previous measures including the Affectometer, Psychological Well-being Scale, PANAS, Depression-Happiness Scale, and WHO-5 [52]. Other multidimensional well-being scales include the “l’Echelle de Bien-Etre” (EBE), which aims to capture variations in well-being following changing environmental and personal circumstances [53]; the Mental, Physical and Spiritual Well-being Scale (MPSWB) which defines well-being as the balanced nourishment of the mind, body, and spirit [54]; the Life Satisfaction Index (LSI) which focuses on morale and adjustment in the elderly [19]; or the Philadelphia Geriatric Center Morale Scale (PGCM) which equals morale with ‘generalized well-being’ [55]. Table 1 organises these measure of multidimensional well-being into categories, to illustrate the variable coverage of diverse dimensions with relatively little overlap between the individual measures.

### Table 1. Dimensions of multidimensional well-being scales.

<table>
<thead>
<tr>
<th>Captured well-being dimensions</th>
<th>SPWB</th>
<th>WEMWBS</th>
<th>EBE</th>
<th>MPSWB</th>
<th>LSI</th>
<th>PGCM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social</td>
<td>Satisfying interpersonal relationships</td>
<td>Social connectedness</td>
<td>–</td>
<td>Positive relationships with others</td>
<td>–</td>
<td>Lonely, dissatisfaction</td>
</tr>
<tr>
<td>Social</td>
<td>Competence</td>
<td>–</td>
<td>–</td>
<td>Environmental mastery</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Social</td>
<td>Autonomy</td>
<td>–</td>
<td>–</td>
<td>Autonomy</td>
<td>Resolution, fortitude</td>
<td>–</td>
</tr>
<tr>
<td>Psychological</td>
<td>Self-acceptance</td>
<td>–</td>
<td>–</td>
<td>Self-acceptance</td>
<td>Positive self-concept</td>
<td>–</td>
</tr>
<tr>
<td>Psychological</td>
<td>Personal development</td>
<td>–</td>
<td>–</td>
<td>Personal growth</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Psychological</td>
<td>–</td>
<td>–</td>
<td>Purpose in life</td>
<td>–</td>
<td>Attitudes to own aging</td>
<td>–</td>
</tr>
<tr>
<td>Mental</td>
<td>Clear thinking</td>
<td>–</td>
<td>Mental activities</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Mental</td>
<td>Energy</td>
<td>–</td>
<td>–</td>
<td>Zest</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Mental</td>
<td>–</td>
<td>Positive affect</td>
<td>Mood tone</td>
<td>–</td>
<td>Positive and negative affect</td>
<td>–</td>
</tr>
<tr>
<td>Mental</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Agitation</td>
<td>–</td>
</tr>
<tr>
<td>Physical</td>
<td>–</td>
<td>Health perception</td>
<td>Physical symptoms</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Spiritual</td>
<td>–</td>
<td>–</td>
<td>Spiritual activities</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

EBE: L’Echelle de Bien-Etre; LSI: Life Satisfaction Index; MPSWB: Mental, Physical and Spiritual Wellbeing Scale; PGCM: Philadelphia Geriatric Center Morale Scale; SPWB: Scale of Psychological Wellbeing; WEMWBS: Warwick–Edinburgh Mental Wellbeing Scale.

### Integrative phase

The World Health Organisation (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” and mental health as “a state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community” [56]. These highly inclusive definitions of well-being and mental health span both poles of the spectrum, i.e. illness or the absence thereof as well as optimum or peak states.
Researchers, mainly in psychology, have devised equally comprehensive and overarching definitions of well-being and health, i.e. of a good life, by including components of all previously outlined approaches. While the medical and psychological approaches are usually covered, the economic approach is represented to a lesser degree. This varying emphasis is partly supported by empirical research showing that the goodness of life is commonly judged by people according to happiness, meaning, and – to a lesser extent – wealth [57].

Table 2 maps some examples of good life conceptualisations. While their constituent components widely overlap some differences also remain, e.g. physical health is only included in one definition [58,59]. Differences between good life concepts may arise from their target population, e.g. Lawton’s (1983) concept is specifically developed for older people [60], or from their cultural background, e.g. a concept developed in Asia includes conformity with conventions [61] while one developed in the United States includes ‘a life dedicated to achieving for the sake of achievement’ in its dimensions of the good life, or “Authentic Happiness” [62]. These overarching definitions of the good life have no corresponding measurement tools but come with recommendations for combinations of varying published or unpublished scales for their assessment.

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Wellbeing (i.e., overall feeling about one’s being)</td>
<td>–</td>
<td>Psychological wellbeing</td>
<td>–</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Satisfaction with life</td>
<td>Life satisfaction</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Happiness</td>
<td>Happiness (i.e., existential feeling of cheerfulness and harmony)</td>
<td>Positive and negative affect</td>
<td>–</td>
<td>Pleasant life (i.e., hedonistic orientation to positive emotions and pleasures)</td>
</tr>
<tr>
<td>Meaning</td>
<td>Meaning in life</td>
<td>Religious commitment</td>
<td>–</td>
<td>Meaningful life (i.e., belonging to and serving something larger than oneself)</td>
</tr>
<tr>
<td>Balance</td>
<td>Biological balance of the body, reflecting overall physical health</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Realize potential</td>
<td>Realizing life potential</td>
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In the integrative approach, positive mental health receives explicit attention. This added focus on the positive instead of just on deficits corresponds with the introduction of a recovery orientation in mental health research and practice as well as with the emergence of the academic discipline of positive psychology. Both developments provide an important context for the good life approach in a mental health context [63].

However, the concept of positive mental health is also far from uniform. One proposed organisation identifies six models of positive mental health from the literature [64]: (i) ‘above normal’, i.e. supremely functioning, empathic, socially competent, resilient, self-actualised, future oriented, autonomous and self-aware; (ii) ‘positive psychology’, i.e. character strength, talents and enablers; (iii) ‘maturity’, i.e. reflecting theories of life time development with greater maturation reflecting better mental health, (iv) ‘social-emotional intelligence’, (v) ‘well-being’, i.e. happiness depending on genetic, environmental and personality factors; and (vi) ‘resilience’. This suggested classification again stresses how diverse and entangled the concepts of well-being and mental health are and how subjective their classification.

The Complete State Model of Mental Health is another classification proposed to provide clarity for research and practice. This conceptual framework includes both poles of mental health and well-being. Mental illness lies on a spectrum from absent to present. Well-being lies on a spectrum from low to high. This notion of a dual continuum may be particularly relevant in a mental health context, because it highlights that people can experience well-being at the same time as experiencing mental illness. Well-being in this model is conceptualised to include all aspects summarised in the psychological approach i.e. positive affect, satisfaction, psychological well-being according to Ryff’s (1995) comprehensive definition, and social well-being [44,65,66].

**Conclusion and Future Perspective**

There is substantial variation in the definition and measurement of well-being. Probably an integrative approach to the concept best reflects its complexity and may hence be most suitable for use in mental health research and practice.

The emergent understanding of well-being as a multi-dimensional construct mirrors systematic review evidence on the recovery process [67]. Empirical research into
these complex constructs is possible [68,69]. A recent clinically relevant advance in well-being research was the development of a dynamic framework of well-being applicable to people with severe mental illness. [70] This consensus definition of well-being was based on a systematic literature review and qualitative research, and found that improved well-being was equivalent to an enhanced sense of self. This definition links well-being to identity, and provides an empirically defensible basis for understanding well-being in terms of determinants, influences and indicators. The influences are targets for interventions to improve well-being, and the indicators are outcome domains to assess the effectiveness of interventions to support well-being. In practice, the convergence of well-being and recovery may suggest a re-orientation of mental health services towards mainstream sources of well-being. From a recovery perspective, it has been argued that mainstream solutions should be preferred over specialist solutions to mainstream problems [63]. The same may be true for well-being, in that factors such as employment, friendship, exercise, sex, or prayer, are as important for people with severe mental illness as for any other group in society. This is consistent with: the Transcendent Principle of Personhood which states that ‘people with severe mental illness are people’ [71]; the Good Life approach which allows a wide range of factors to be focussed on in potential interventions to improve well-being; and the Complete State Model of Mental Health which acknowledges the possibility of well-being co-existing with mental illness.

One future research focus will need to be on developing reliable and valid measurement tools to capture outcomes consistent with these models. At present, using a combination of established measures is proposed to capture diagnoses of mental illness, functioning, social disability, as well as indicators of well-being such as hope, empowerment, self-esteem, social connection, self-worth or meaning, together with or in addition to broad multidimensional well-being scales.

Specific interventions to target well-being and its associated dimensions, such as self-worth, meaning, or hope [72] will need to be further developed and evaluated. A promising resource to draw on is the academic discipline of Positive Psychology [73]. The promotion of well-being is a focus of this discipline, which has shifted away from ameliorating deficits (e.g. symptoms) towards building positive emotions, character strengths and meaning [74]. There is good evidence that interventions using positive psychology strategies increase well-being and decrease depression in its recipients [75]. One specific intervention based on this body of knowledge is Positive
Psychotherapy (PPT). This intervention draws on a range of resource oriented exercises to improve well-being in its recipient [76]. Initial evidence suggests its usefulness for people with common mental disorders, such as depression [74,76,77], and it may also be promising for people with severe mental illness, such as psychosis [78]. Future research will have to establish the usefulness of positive psychology intervention approaches, including PPT, across a spectrum of mental illnesses.

Disclosure

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51. Stewart-Brown S, Tennant A, Tennant R et al. Internal construct validity of the
Introduces the WEMWBS as a scale that brings together a range of pre-existing assessments for well-being.


Introduces the concept of Authentic Happiness and positive psychology.


*This article describes and scientifically validates the complete state model of health.*


*This systematic literature review provides a consensus definition of recovery and the processes involved in recovery from severe mental illness.*


*This qualitative research identifies a definition of well-being in people with severe mental illness, with a particular focus on the processes involved in improving well-being.*


This systematic literature review provides an overview on randomised controlled trials investigating various positive psychology interventions in different client groups. It also investigates determinants for the effectiveness of the included therapeutic interventions.


End of published paper.
Appendix 2: Data Supplement showing studies excluded after reading the abstract or full paper and reasons for exclusion

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Appendices
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Appendix 3: Topic guide for service user interviews

WELLFOCUS
Phase 1

Developing a model of well-being for people with psychosis

Topic Guide – Service Users Interviews

This interview is to learn about what you think about well-being and how you think it might be improved in people with psychosis. The interview is being recorded on audiotape, any personal details will be removed during transcription, and there are no right or wrong answers - we are interested in your personal view.

Part One [up to 20 minutes]

To start off, Can you all tell me what well-being means for you personally?

Prompt questions:
- What makes life worth living?
- What makes life good for you?
- What has worked for you before to support your well-being?
- What would you advise other people to do to look after themselves and have a good life?

Prompts for specific advices:
- Can you describe ________ a bit further?
- How would that make a difference?
- Why?
- What about ________ is it that increases well-being?
- How could ________ be supported to help you increase well-being

Part Two [up to 40 minutes]

We are thinking of running a well-being group for people with psychosis. I would like to hear what you think about suggestions for four groups of activities.

Prompts (to be asked after each example):
- What do you think about that?
- How would that make a difference in your life?
- Why and how would that change well-being?
- What may be problematic about that?
- What may be positive about that?
- How could that be done so that it is helpful for you?
- Would you change anything about this activity? If so: what?
Focus 1: Identifying and using personal strengths
This involves
• identifying your personal strength (through questionnaires and group discussion)
• developing plans and doing activities that help further develop your strengths
• developing plans and using your strengths to do something that is really meaningful to you (e.g. devoting time to helping someone else with your strength)

Focus 2: Positive emotions, pleasure and enjoyment
This involves
• Cultivating positive emotions by regularly reflecting on good things that happened to you (and very briefly writing this down)
• Learning about how to more fully and consciously enjoy moments or activities, and practising these strategies to increase enjoyment

Focus 3: Engagement and connection
This involves
• Learning how to respond to other people in active and constructive ways
• Planning and doing activities together with another person that builds both their and your own strengths
• Talking to family members about their personal strengths and developing a family tree of strengths

Focus 4: Good memories, optimism and hope
This involves
• Reflecting on bad memories and bitterness and how they affect your life
• Choosing to forgive someone who has offended you in any way, e.g. by writing a letter, and reflecting how forgiveness changes bitter feelings
• Discussing the differing effect of good and bad memories and feelings
• Choosing someone you are grateful for something, expressing your thankfulness, e.g. in a letter, and reflecting on the feeling that brings you
• Thinking about how missed opportunities, failed plans or other disappointments have also had a positive effect in your life

Questions on intervention design:
• How long should one group session be? (maximum length)
• How many sessions should the entire intervention consist of?
• What do you think about separate sessions on psychosis specific issues (e.g. on positive aspects of hearing voices)?
• What do you think about tasks between sessions, something like homework?
• What do you think about the burden of homework?
• How much homework is reasonable to expect?
• What else may be helpful?

Thank you for sharing your views with me.
# Appendix 4: Sociodemographics Form - Service User (SF-SU)

1. Gender
   - □ Male
   - □ Female

2. Date of birth: __________ / __________

3. How do you describe the ethnic group to which you belong?
   - □ White British
   - □ White Irish
   - □ White Other
   - □ Black/Black British-African
   - □ Black/Black British-Caribbean
   - □ Black Other
   - □ Asian/Asian British-Indian
   - □ Asian/Asian British-Bangladeshi
   - □ Asian/Asian British-Pakistani
   - □ Asian/Asian British-Other
   - □ Mixed, White & Asian
   - □ Mixed, White & Black African
   - □ Mixed, White & Black Caribbean
   - □ Chinese
   - □ Other
   - Please specify:________________________

4. What is your country of birth? __________________________________________

5. Which languages do you speak fluently (in addition to English)?
   ___________________________________________________________

6. How long have you used mental health services? ________ Years ________ Months

7. What type of accommodation do you live in?
   - □ Owned
   - □ Rented (Private)
   - □ Rented (Council or Housing Association)
   - □ Supported Housing
   - □ Living with family / friends
   - □ Homeless
   - □ B & B / Hostel
   - □ Other
   - Please specify:________________________

8. What is your marital status?
   - □ Single
   - □ Married
   - □ Divorced
   - □ Civil Partnership
   - □ Co-habitting
   - □ Separated
   - □ Widowed
   - □ Other
   - Please specify:________________________

9. What is your highest qualification?
   - □ No formal qualifications
   - □ GCSE or equivalent
   - □ A-level or equivalent
   - □ NVQ level: __________
   - □ BTEC level: __________
   - □ Higher national certificate/Diploma
   - □ Bachelors degree
   - □ Masters degree
   - □ Doctoral degree
   - □ Relevant professional training
   - Please specify:________________________

10. Current employment status
    - □ Full-time paid work
    - □ Part-time paid work
    - □ Voluntary Job
    - □ Student
    - □ Unemployed
    - □ Other
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<tr>
<td>Did the groups you attended help you to develop your personal strengths?</td>
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<tr>
<td>Did the groups you attended help you to foster positive relationships with other people?</td>
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<tr>
<td>Did the groups you attended help you to develop meaning in your life?</td>
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</tr>
<tr>
<td>Did the groups you attended help you to develop a more positive sense of self?</td>
<td></td>
</tr>
<tr>
<td>How much were you engaged with the exercises in the groups?</td>
<td></td>
</tr>
<tr>
<td>Did you find the exercises in the groups helpful?</td>
<td></td>
</tr>
<tr>
<td>Did you find the ongoing tasks during the week helpful?</td>
<td></td>
</tr>
<tr>
<td>Did you find the phone calls you received between sessions helpful?</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 6: Researcher rated process and fidelity assessment form (session 3)

<table>
<thead>
<tr>
<th>SESSION 3 - Good Things</th>
<th>Engagement in session overall session</th>
<th>Did not attend</th>
<th>Participant</th>
<th>FIDELITY rate what the therapist has covered in session</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exercise in session experienced as beneficial</td>
<td></td>
<td></td>
<td>Intervention components</td>
</tr>
<tr>
<td></td>
<td>Homework undertaken last week</td>
<td></td>
<td></td>
<td>Welcome &amp; recap</td>
</tr>
<tr>
<td></td>
<td>Homework last week perceived as beneficial (client feedback)</td>
<td></td>
<td></td>
<td>Warm up: stand up who</td>
</tr>
<tr>
<td></td>
<td>Estimate of behavioural intent to do homework</td>
<td></td>
<td></td>
<td>Introduction to good things</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>therapist gives personal example</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>filling out first good things card</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>group reflection on good things</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>preparing for ongoing task at home</td>
</tr>
</tbody>
</table>

| 0 = complete rejection   | 1 = somewhat engaged                  | 2 = very engaged |
| 0 = not done             | 1 = partly done                       | 2 = done         |
| 0 = unsure               | 1 = irrelevant/neutral                | 2 = beneficial   |
| 0 = great                | 1 = enthusiastically great            |                 |
Appendix 7: Topic guide for process evaluation interviews and focus groups

INSTRUCTIONS FOR RESEARCH WORKER

Aims
1) To explore acceptability of the intervention and identify suggestions for adaptations and improvements to the model
2) To validate the model for increasing wellbeing through the WELLFOCUS intervention
3) To establish trial parameters

Take along a copy of the WELLFOCUS manual and a WELLFOCUS journal containing all handouts to use throughout the interview to make sure questions cover the WELLFOCUS intervention.

Q: bold framed questions are the key questions which we should try to cover in the focus groups

INTRODUCTION

Thank you for participating in the WELLFOCUS group. This interview/focus group is to learn about what you think about the WELLFOCUS positive psychotherapy you have received during the last 3 months.

We will cover
1. what you have experienced during the group
2. therapy
3. how we should do things in the future

There are no right or wrong answers - we are interested in your personal view. What you say will help us to further understand how the therapy works and how we can improve it. The interview is being recorded on audiotape. Any personal details will be removed during transcription, and the tapes destroyed after transcribing. Everything you say will be kept confidential.

Please be careful that you also keep whatever is said in the focus group/interview confidential, and please turn mobile phones off or put them on silent.

INTERVIEW QUESTIONS

INSTRUCTIONS FOR RESEARCH WORKER

Refer to WELLFOCUS journals which participants have brought with them or, alternatively, hand them a spare copy for orientation and to help remember the group components.
Section 1: Intervention components

Q1: Looking back at the groups you have attended is there anything that was especially useful for you, anything you particularly liked? What has that changed for you? Examples?

Q2: Is there anything you particularly disliked?

Q3: How were the key tasks perceived:
   - Positive responding
   - Positive introduction
   - Savouring
   - Good things
   - Identifying and using personal strengths
   - Activities with others
   - Forgiveness
   - One door closes, another door opens
   - Gratitude

INSTRUCTIONS FOR RESEARCH WORKER

Go on to ask specifically for those parts of the intervention that have not come up spontaneously so far. Use the following questions as applicable. Use prompt for each as above.

Q4: What did you think about the Ongoing Exercises? (any recommended changes, why, how?)

Q5: How did you find the between session phone calls?

Q6: How useful did you find the WELLFOCUS journal? How useful was it having it in advance? Are there any changes you think we should make to it?

Q7: How useful were the handouts in the sessions?

Q8: What did you think about the way the group was delivered? (consider: understandability, group length, group size, waiting times, therapist characteristics and interaction)

Q9: Was there anything you covered in the groups that you found upsetting? Please explain what and why.

Section 2: WELLFOCUS model and mediators

Q10: How far did taking part in the group help you to increase positive experiences in your life? What helped with this? How?

Q11: How far did taking part in the group help you to understand or develop your personal strengths? What helped with this? How?

Q12: How far did taking part in the group help you to foster positive relationships with other people? What helped with this? How?

Q13: How far did taking part in the group help develop meaning in your life? What helped with this? How?

Q14: Overall how do you think attending this group has made a difference for you? In what ways? Please explain.
Section 3: Implementation

Q15: What do you think about the way you were invited to take part?
Q16: What do you think about the way you were randomly chosen to receive the group or not?
Q17: What do you think about the questionnaires you completed?
Q18: Did you miss any sessions? If yes, could you tell me why? What could have helped you to come to more or all of the sessions? What would we need to change to make this group more suitable and/or interesting for you?
Q19: Any other comments?

INSTRUCTIONS FOR RESEARCH WORKER

End group by reminding participants of confidentiality.
Thank participants and organise payments.