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The Optimisation of Experience Sampling Protocols in People with Schizophrenia

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Abstract

Experience sampling methodology (ESM) involves completing questionnaires during daily life and has been used extensively in people with schizophrenia to assess symptoms and behaviours. Despite considerable advantages over interview measures, there is limited information about its external validity. Our aim is to investigate whether ESM protocol implementation is affected differentially in people with schizophrenia and healthy individuals by factors such as mood, medication and symptoms which would have implications for validity. Fifty-three people with schizophrenia and fifty-eight controls from the general population completed seven ESM questionnaires per day for six consecutive days. Compliance and acceptability, including overall experience, training and disruption of normal routines, were recorded. Overall questionnaire completion rate in people with schizophrenia was comparable to controls (i.e. over 70%). People with schizophrenia completed significantly fewer questionnaires in the morning but did not show fatigue effects over the experience sampling period. Excluding questionnaires in the morning did not significantly alter the findings. In the schizophrenia group medication level and symptoms did not influence adherence. However, higher disruption was associated with reduced questionnaire completion in this group. These findings suggest that minimising disruption may enhance validity and completion rates. ESM is a valid methodology to use with people with schizophrenia.

Highlights

- This is the first study to examine the validity of an ESM protocol.
- People with schizophrenia show similar protocol compliance to healthy controls.
- People with schizophrenia complete fewer questionnaires in the morning.
- Medication and symptom levels do not influence questionnaire completion rates.
- Levels of reported disruption were associated with reduced questionnaire completion.

1. Introduction

Experience sampling methodology (ESM) is an assessment method developed to overcome the limitations of experimental and retrospective measures. Participants complete repeated assessments over several days, in response to randomly timed prompts (Kimhy, Myin-Germeys, Palmier-Claus, & Swendsen, 2012). ESM has many features which recommend it for use in studies examining mental health problems. Assessments are completed “in the moment” so do not rely on retrospective memory and are collected as part of a participant’s everyday life. ESM questionnaires assess behaviours, emotions and thoughts over time - providing valuable insight into the dynamics of symptom experiences in everyday life. This enables the identification of modifiable treatment targets with high relevance to everyday life. The large number of data points collected per individual compared to a single questionnaire also maximises the robustness of the findings and minimises the influence of extreme responses in statistical analyses.

Although ESM has many advantages there are concerns about its potential burden on participants (Kimhy et al., 2012). There are a small number of studies that report feasibility data for people with schizophrenia. Studies assessing positive symptoms find over 80% completion rates of six questionnaires per day for a week (Kimhy, Vakhrusheva, Liu, & Wang, 2014; Palmier-Claus et al., 2012). A review of ESM in studies including people with severe mental disorders reported similar compliance rates ranging from 72-81% (Kimhy et al., 2012). These studies also report a minimum threshold of questionnaires to be completed for inclusion in the study (set at 20 or 33%), the number of excluded participants ranged from 1-9 (Oorschot et al., 2013). This study extends these current findings by examining compliance rates across time in both people with schizophrenia and controls as differential rates of responding may introduce bias. Furthermore, although missing questionnaires are reported in every ESM study, the impact of this missing data on the conclusions drawn has not yet been examined. This study investigates the effect of missing questionnaires on mood ratings and considers the implications for future ESM protocols.

This study contributes to the literature by examining several factors which may influence this compliance and therefore reduce the validity of ESM studies. For example, assessments conducted over several days may be affected by fatigue and/or adherence may fluctuate resulting in systematic patterns of missing data. Studies have shown that antipsychotic medication affects the sleep-wake cycle of people with schizophrenia and therefore may impact adherence rates (P. Afonso, Brissos, Canas, Bobes, & Bernardo-Fernandez, 2014; Pedro Afonso, Figueira, & Paiva, 2014). In addition mood or low motivation may be implicated in diurnal variation in completion rates. This could reduce the representativeness of the assessments, especially in comparison to healthy controls. Factors such as medication dosage and symptom levels may also act as moderators of protocol compliance i.e. medication may moderate the relationship between symptom levels and

questionnaire completion rates. These more complex relationships are yet to be investigated in the literature.

Despite the high potential utility of ESM protocols, investigations of the validity of these data are lacking. In particular, one controversial issue that ESM research has not dealt with is responsivity. This refers to participants changing their typical behaviours to be more available for the questionnaires or in response to some of the questions asked. This can limit the ecological validity of the findings and this study aimed to address this to increase confidence in the conclusions drawn from this methodology. Furthermore, two previous studies have reported the experience of the participants in these studies as acceptable, although both only included a sample size of 10 (Depp et al., 2010; Kimhy et al., 2006). This has yet to be examined in a larger sample of people with schizophrenia and controls and replicating this finding was a further aim of this study.

The current study therefore aimed to thoroughly assess the feasibility and internal validity of ESM studies for the first time by addressing the following research questions:

- Are there different compliance rates over time in people with schizophrenia compared to controls?
- Do participants indicate significant changes to their usual routines as a result of completing the ESM study which may indicate responsivity?
- Do participants find the experience of taking part in an ESM study acceptable?
- Do medication, symptoms or levels of disruption influence compliance and therefore potentially confound the results? Are there important moderating relationships between these variables?
- Do missing questionnaires significantly alter the overall ratings of mood?

2. Method

2.1 Sample

Participants with diagnoses of schizophrenia were outpatients recruited from community mental health teams in South London using the following inclusion criteria: (i) DSM-IV diagnosis of schizophrenia or schizoaffective disorder, (ii) aged 18-65yrs, (iii) good command of the English language. They were excluded if they had: (i) primary DSM-IV diagnosis of substance abuse, (ii) severe learning difficulties (iii) changes to medication in the last 6 weeks.

Control participants were recruited from the general population using online advertisements, community links Inclusion criteria: (i) no current or history of mental health problems according to the MINI (see below) (ii) aged 18-65yrs (iii) good command of English.

2.2 Measures

2.2.1 Mini International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998) was used to screen for current and past mental health problems in the control group.

2.2.2 ESM questionnaires were designed to assess experiences of pleasure, motivation and socialising in everyday life. Positive and negative affect were measured alongside these variables as a potential moderator of symptoms in schizophrenia (Oorschot, Lataster, Thewissen, Lardinois, et al., 2012; Oorschot, Lataster, Thewissen, Wichers, & Myin-Germeys, 2012; Thewissen et al., 2011). Participants were asked to respond to all ESM questions using either Likert scales (1-7) or category boxes e.g. "Right now I feel anxious" 1 (not at all)-7 (very much so). The questionnaires, methodology and device were reviewed and received approval from a service user advisory group within the Service User Research Enterprise (Rose & Wykes, 2001).

2.2.3 Experience Feedback Questionnaire (EFQ) was developed using participatory methodology (Evans et al., 2012) with contributions from service users. It was then reviewed and approved by a service user advisory group to ensure it covered relevant concerns. The questionnaire identified issues that might affect disruption (ease of use, enjoyment, embarrassment etc.) as well as directly asking about disruption to typical routines or activities. Items were rated on a 7-point Likert Scale and averaged to provide an acceptability score for the overall experience and disruption. A score of 4-7 (from 1-7) was considered acceptable.

2.2.4 Potential Moderators of Protocol Compliance

Symptom severity in the schizophrenia group was assessed with the **Positive and Negative Syndrome Scale (PANSS)** (Kay, Opler, & Lindenmayer, 1988). We derived five symptom domains according to (Wallwork, Fortgang, Hashimoto, Weinberger, & Dickinson, 2012) as this produces separate scales for disorganisation and negative symptoms which may have distinct effects on compliance (Cella, Reeder, & Wykes, 2014). All participants completed a **demographic questionnaire** which collected information regarding age, gender, ethnicity and medication, dosages were checked on electronic medical records and **chlorpromazine equivalent dosages** were calculated (Woods, 2003).

2.3 Procedure

The experience sampling questionnaire was administered using a small portable device called a PsyMate (Maastricht University) with a touch-screen that displays questionnaires and records answers. At the initial session participants were shown how to use the PsyMate and completed a practice assessment as well as the PANSS and demographic questionnaire. The PsyMate was used for the next 6 days and was programmed to beep 7 pseudo-random times a day between 8.30am and 10pm with at least 45mins between beeps. A 20 minute window was allowed to complete the questionnaire after the prompt. If the questionnaire was not completed within this time it was recorded as "missed".

During the ESM assessment week the researcher contacted the participant (generally on the 2nd day) to check if there had been any problems. After six days the participant returned for a debrief session and completed the Experience Feedback Questionnaire and were reimbursed for their time. All participants provided written informed consent and approval was received from a Research Ethics Committee (12/LO/1524 and 13/LO/1791).

2.4 Analyses

2.4.1 Completion rates: The median and interquartile range of the overall completion rate (% questionnaires completed) was reported to describe the data variance. A minimum threshold of 20% of overall questionnaires completed was set to ensure adequate external validity of the ratings (Oorschot et al., 2013). The average percentage of questionnaires completed for each beep (1-7) and day (1-6) is reported separately and was used to index fatigue. The average percentage of questionnaires completed at each beep and day were compared within-groups using paired t-tests to ascertain significant reduction in either group. Those identified as significantly reduced within each group were compared between groups using a one-way Analysis of Variance (ANOVA) to establish whether compliance rates are significantly altered in one group which may limit the validity of between-group comparisons in the findings from the questionnaire.

2.4.2 Feedback on the Experience of Participation: The ratings of disruption (responsivity), the training provided and the experience of taking part were reported for both groups.

2.4.3 Potential Moderators of Compliance (symptoms, mood, medication and disruption): Effects of medication, symptom severity and disruption was tested on overall completion rates and on days or beeps identified as significantly lower using Pearson's correlation analyses and Spearman's Rank correlations for any non-parametric data. Correlations which are moderate ($r=0.4$) or higher were considered indicative of reduced validity of the data due to a disruptive influence of this factor. A power calculation determined that 46 people in each group were sufficient to detect a correlation of this size. Disruption, symptoms and chlorpromazine equivalents effects on low and high adherence were also tested using one-way ANOVAs.

2.4.4 Effects of compliance on ESM measures Mean values of positive and negative affect were calculated as these ratings provided the largest pool of data. These calculations were repeated after bootstrapping the data using the *bootstrap* Stata command (StataCorp, 2009) to randomly select 5 questionnaires per day. The calculations were also repeated after specifically excluding those time-points with the lowest completion rates. Both of these decisions were data-driven according to the pattern of responding identified in the schizophrenia group. This analysis identified any significant alterations to these values as a result of this missing data. The times with lower completion rates were compared to those which were not reduced using a paired t-test analysis.

3. Results

Fifty-four people with a diagnosis of a schizophrenia spectrum disorder and 58 healthy controls took part in the study. Only 5 (9%) people with schizophrenia and 1 (2%) control completed fewer than 20% of questionnaires and were therefore excluded. Table 1 presents the demographic characteristics of the two final groups. There were no significant differences between the people who were excluded and those included in the analyses on age, medication or symptoms except lower PANSS depression in those excluded ($p < 0.05$).

-----Table 1 about here-----

3.1 Questionnaire Completion

There was no difference between groups in the overall completion rate ($F(1,105)=1.80$, $p=0.18$). Participants with a diagnosis of schizophrenia completed, on average, 71% (IQR=29.5, min: 32, max: 100) of questionnaires compared to 79% (IQR=26, min: 21, max: 100) in the control group.

A within-group analysis revealed that people with schizophrenia respond significantly more often to beeps 3, 5 and 6 compared in pair-wise analyses to beeps 1, 2, 4 and 7 ($p < 0.05$) (see Figure 1). However, the completion rates for these beeps were not significantly lower compared to the control group, with the exception of beep 7 ($F(1,105)=4.50$, $p=0.04$).

-----Figure 1 about here-----

Fatigue effects were identified by examining response rates at different days of the week using within-group analyses (See Figure 2). We expected poorer responding at the end of the week if fatigue is present but response rates did not vary considerably in either group, although controls did complete significantly fewer questionnaires on day 3 compared to day 2.

-----Figure 2 about here-----

3.2 Experience Ratings

The average ratings for each section of the questionnaire are reported in Table 1, some items were reversed so a higher score always reflects a better rating. In the schizophrenia group all of the participants found taking part in the assessment acceptable while 98% of control participants rated this experience as such. Disruption to the individual's typical week was rated as minimal by 94% of people with schizophrenia and 100% of the control participants. The people in the schizophrenia group who reported high disruption ($n=3$) did not complete fewer questionnaires at Beeps, 1, 2 or 7 ($F(1,48)=0.17, 0.27, 1.69$ respectively, $p > 0.05$) than those who rated disruption as minimal ($n=46$). However, there was a significant, moderate association between disruption ratings and questionnaire completion rates in the schizophrenia group ($r=0.41$, $p=0.003$). Disruption ratings did not correlate with medication

or symptoms and therefore partial correlations examining the moderating influence of these variables on the association with completion rates were not performed.

3.3 Is validity affected?

3.3.1 Potential moderators of adherence In the schizophrenia group the overall percentage of questionnaires completed did not significantly correlate with chlorpromazine equivalent dosage (Spearman's $\rho = -0.04$, $p = 0.75$), total PANSS score ($r = 0.02$, $p = 0.91$) or any PANSS subscales ($r = -0.17$ - 0.22 , $p = 0.14$ - 0.60). There were no significant correlations between Beeps 1, 2, 4 or 7 (which had significantly reduced completion rates) and medication (Spearman's $\rho = -0.08$ - 0.11 , $p = 0.37$ - 0.81), or symptoms ($r = -0.23$ - 0.18 , $p = 0.11$ - 0.91). Participants in the schizophrenia group who completed fewer than 50% of the beeps at time-point 1 and 2 did not significantly differ from the other participants in their levels of medication ($F(1,47) = 0.21$, $p = 0.65$), total PANSS score ($F(1,47) = 0.16$, $p = 0.69$) or any PANSS subscales ($F(1,47) = 0.16$ - 3.73 , $p = 0.06$ - 0.69).

3.3.2 Disruption effects on ESM values The data was bootstrapped to randomly select 5 beeps a day and to specifically exclude beeps 1 and 2 and the means across the week were calculated (see Table 2). The findings suggest that a lower completion rate at certain times of day does not alter the conclusions drawn from the data compared to the full dataset or randomly selected fewer data points. Although the mean value for positive, not negative, affect was significantly reduced at Beeps 1 + 2 compared with the rest of the day in the schizophrenia group ($t(49) = -2.48$, $p = 0.02$).

-----Table 2 about here-----

4. Discussion

We examined for the first time the external validity of ESM in relation to response rates at each beep. This revealed that people with schizophrenia show diurnal variation in their completion rates with fewer questionnaires completed in the morning. We know that there was no effect of this systematic bias on the ratings made on the ESM device. This is important as the adherence to these beeps was also significantly lower in the schizophrenia group compared to controls so could have been a source of bias when comparing ESM findings between these groups. However, our analysis of mean values excluding these data points suggested the impact on validity is minimal in both these groups. As positive affect did show a significant reduction in the morning compared to the rest of the day in the schizophrenia group, it is still important to sample this time period so as to capture the full range of mood experienced.

As there was no effect of medication dose or symptom levels on completion rates there is no evidence that including individuals with chronic schizophrenia and a range of symptoms would be detrimental to validity of this type of study. However, this may not be the case for other studies which are sampling different outcomes. Our interpretation is that

the diurnal bias effects we discovered may be due to a disrupted sleep-wake cycle in schizophrenia resulting in a later wake-up time (Pedro Afonso et al., 2014).

Disruption to the week was only considered to be negative in a very small proportion of individuals, suggesting minimal responsivity, which is encouraging for future research. However, it was associated with reduced questionnaire completion in the schizophrenia group which may introduce some bias. The experience of disruption is not related to medication, symptoms or particular times of day in this study. These findings suggest that medication and symptoms do not therefore act as moderators of the relationship between the experience of disruption and completion and therefore do not account for this association as may have been hypothesised initially. However, the narrow range of disruption ratings in this study limits this conclusion and the influence of medication and symptoms on other associations with completion rates e.g. sleep should be investigated in future research. The vast majority of ESM studies often fail to record the experience of taking part from the service user's perspective and therefore disruption is often not controlled for in analyses. Not only is gathering more information about the service-user experience valuable for experimental design but the findings from this study suggest it is important to consider how disrupted the individual was during the week when interpreting the results of an ESM study. In particular, future studies may wish to ask more directly about responsivity and specifically how much of an influence the participant felt the experience of measuring these constructs had on their responses.

It is becoming more common for service-user groups to review experimental protocols and questionnaires prior to conducting a study (Reeder et al., 2015). However, there is very limited information in the experience sampling literature on the experience feedback and this information was not present in the literature. Although this may add to the assessment time we feel that the development and optimisation of a method that it is not only patient friendly but also patient informed requires this type of feedback to be collected routinely.

Future research should build on this work by assessing the acceptability of mobile monitoring and interventions in people with a wider range of mental health problems. The ability to monitor the symptoms of people in everyday life is important in the prevention of relapse, particularly for people with psychosis as relapse is predictive of a worse long term prognosis for that individual (Kane, 2013). With this method now being largely implemented via mobile phones and the information collected becoming instantly available to clinicians the potential to adopt ESM in therapeutic contexts is becoming more apparent and increasingly promising.

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