A qualitative study exploring behavioural change intervention in Congenital Heart Disease

Lara C.F. Tosunlar, Phuoc Duong, Chris Tack, Jacky Jones, Natali Chung, Joseph Chilcot, Zoe Moon, Alessandra Frigiola

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ABSTRACT

Introduction: Medical advancements have significantly improved survival of patients with Congenital Heart Disease (CHD). Consequently, an aging CHD population are more susceptible to cardiac-related complications and co-morbidities. Early intervention, with individually-tailored, patient-centred approaches targeting physical activity, diet and stress, can reduce these modifiable risks. Lifestyle Intervention Programmes (LIP) are safe, cost-effective interventions, aiming to promote positive health behaviour change. CHD LIP efficacy research is limited.

Objective: This study aims to explore patients’ expectations and experiences to better identify determinants of patient adherence and aspects of LIP that need developing.

Methods: Qualitative study using semi-structured interviews. Group 1 included seven patients who had not taken part in a LIP to establish views and expectations of LIP. Group 2 included five patients who participated in 3-month pilot LIP at Guy’s and St Thomas’ to gather feedback on their experience.

Results: Three key themes were identified from Group 1 data: Expectations of Lifestyle Intervention Programme and Intentions to Engage, Views about Online Support for Lifestyle Intervention Programme, Patient Anxieties about Exercise Damaging their Heart. Four key themes were identified from Group 2 data: Insufficient Dietary Information, Brilliant Intentions Marred by Barriers, Pertinence of Plans to Patients, Positive Patient Experiences and Outcomes.

Conclusions: This study provides new insight into beliefs, expectations and experiences of patients with CHD. Findings support the value of LIP for CHD and inform recommendations for LIP development including need for health psychology, dietetic support, more education, greater focus on techniques to address barriers to adherence and scope for specifically-designed App.

1. Introduction

Congenital Heart Disease

Congenital Heart Disease (CHD) comprises a variety of anomalies and, with over 1% of new-borns affected, is the most common major birth defect [1]. Medical and surgical advancements have significantly extended life expectancy [2]. Consequently, an aging CHD population are at greater risk of developing cardiac-related complications and co-morbidities common to the general population [3].

Patients with CHD experience significant physical and mental stress [4,5], commonly have sedentary lifestyles and physical deconditioning [6] and require personalised dietary programmes but are often unaware of how best to eat [7]. These factors are associated with obesity, metabolic disorders, osteosarcopenia, autoimmune disorders, type-2 diabetes and mental health conditions [8]. In addition, chronic stress has been linked with poorer quality of life and greater frequency of medically unexplained symptoms; such as fatigue, palpitations, chest pain and anxiety. Thus, increasing the risk of developing cardiac-related complications and co-morbidities; including hypertension, stroke, and coronary

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

* Corresponding author. Department of Cardiology, ACHD, Guy’s and St Thomas’ Hospital, London, UK.

E-mail address: alessandra.frigiola@gmail.com (A. Frigiola).
artery disease (CAD).

Cardiac risk factors, including smoking, obesity, hypertension and diabetes, are commonly seen within the general population, highlighting the need for primary prevention [8] and the current trend in healthcare, to cultivate primary and secondary prevention schemes, is particularly pertinent for patients with lifelong conditions like CHD. Early intervention can help reduce these risks, as they are recognised to be amenable to lifestyle modification; including increased physical activity, improved nutrition and stress management [3]. Therefore, lifestyle intervention programmes, which minimise chronic stress, modify body composition and promote positive health behaviours, hold promising potential [9]. With the proviso that specific factors, particularly disease severity, are taken into consideration when designing personalised regimens, interventions that incorporate physical activity and nutritional guidance are regarded to be low-risk and high-benefit for patients with CHD.

Positive health behaviour change, is recognised as a key component of lifestyle intervention programmes aimed to reduce cardiac risk factors [8]. At present, no single psychological model fully explains physical activity and dietary behaviour. However, health behaviour theories, including Health Belief Model (HBM) [10], Theory of Planned Behaviour (TPB) [11,12] and COM-B Behaviour Change Model [13] have identified key behavioural predictors; such as motivation, lifestyle, health knowledge and awareness, susceptibility, socio-economic status and self-efficacy. Although, it is recognised that no single model can explain all variance in any behaviour, behavioural change models remain fundamental to the development of efficacious theory-based LIPs.

Poor adherence remains widespread within LIPs due to the presence of barriers which often impede adherence and positive behaviour change [14,15]. Barriers are a key component within the HBM and can include high anxiety, low mood, poor motivation, lack of time, low levels of knowledge, societal pressures, socioeconomic constraints, physical limitations and health fears or misconceptions [3]. Enabling factors that positively and negatively affect behaviour to be identified, models remain fundamental to the development of efficacious theory-based LIPs.

The TPB proposes behavioural intention can predict behaviour [11,12]. However, this theory does not consider how demographic or personality factors affect intentions, nor the influence of habits or emotions [12]. Overall, intention has been recognised to precede the act of carrying out physical activity but is insufficient in itself to predict or explain physical activity behaviour [16–19]. Consequently, research has drawn attention to the problem of the “intention-behaviour gap”; a concept that captures the lack of straightforward translation of intentions into behaviour. Health psychologists have created techniques to help bridge this well-recognised gap, including commitment to achieving health goals and employment of action plans; namely “implementation intentions” [20,21]. It follows, therefore, that these techniques have potential value within LIPs; to increase adherence and positive behaviour change [7].

The COM-B is currently used extensively in the field of behaviour change [22]. It comprises three core components, which in turn predict behaviour; Capability, Opportunity and Motivation. Though criticised for being difficult to operationalise and test, due to its aspiration for inclusivity, COM-B is recognised to provide a useful and comprehensive framework for policy and intervention design. The Behaviour Change Wheel (BCW) aids identification of specific Behaviour Change Techniques (BCTs), which are most likely to be effective. Hence, it was used to characterise interventions within 2010 Department of Health's tobacco strategy and NICE guidelines on obesity [22].

Research that focuses on lifestyle intervention for patients with CHD remains sparse. Our study aimed to identify determinants of patients’ adherence that could be developed to promote higher levels of adherence to inform changes to the design of a specific LIP for patients with CHD.

2. Methods

2.1. Design

A qualitative study was conducted using in-depth semi-structured interviews, with two groups of patients with CHD attending their routine clinical appointment in a large urban NHS Foundation trust.

2.2. Participants

Participants were recruited by the researcher (LT) between January and July 2020. Patients were invited to participate when they attended their clinic appointment. The study was explained to those who expressed an interest and, once verbal agreement was obtained, patients received the Participant Information Sheet. Patients were given opportunity to ask questions before giving consent, by signing the Informed Consent Form.

Group 1 consisted of seven patients who attended their out-patient clinic appointment for routine follow-up, with no previous experience of participating in a LIP. Group 2 consisted of five patients who took part in a three-month pilot LIP. Exclusion criteria included the presence of established lack of mental capacity.

2.3. Intervention

The locally developed LIP design was based on clinical experience and developed in accordance with AHA guidelines [6]. Local ethical approval was obtained for the study. The research team enrolled eligible patients when they attended their hospital appointment for a cardiopulmonary exercise test (CPET). Those interested in participating in the LIP were consented and the following non-invasive, bloodless tests were carried out using BioTekna medical technology:

Photoplethysmography (PPG Analysis)
Bio-impedance (BIA-ACC Device)

Photoplethysmography (PPG) is a non-invasive method for assessing the blood volume pulsations by detection and temporal analysis of the tissue-scattered (absorbed) optical radiation. Blood flow was monitored, at the fingertip in our study, with simple and convenient PPG contact sensors. We used PPG methodology to measure within minutes the heart rate variability (HRV), a non-invasive marker of health and wellbeing, which reflects activity of the vagus nerve, the primary nerve of the parasympathetic nervous system [23, 24].

Whilst we used BIA-ACC (bio-impedance) to compute the body composition within seconds. This device applied alternating currents, using two different frequencies, 50 and 1.5 kHz (bi-frequency measurement method). Patients laid supine on a flat, nonconducting surface; two electrodes were applied on the dorsal surface of the right hand, and two electrodes on the dorsal surface of the right foot. Variables such as muscle mass, fat mass, bone mass, total body water and extracellular body water were obtained [25–27].

Personalised exercise regimens were discussed, in relation to test results, with the CHD trained cardiologist (research fellow) and physiotherapist who conducted the LIP. Patients also received a generic printout of a day’s intake based on one of four recommended diets: Scandinavian, Circadian, Okinawan or Mediterranean [28,29]. Such immediate feedback was designed to engage patients and promote a collaborative approach to achieving desirable behaviour change.

Patients were invited to appointments on a monthly basis for three months, in order to review progress. On each visit they received updated BioTekna assessment and a one-to-one consultation with the physiotherapist to refine their LIP. At the end of the three months, CPET was repeated. Patients were able to contact the physiotherapist and research fellow via email in between appointments if needed.
2.4. Data collection

Interviews were conducted the same day as the clinic appointment, preventing additional travel to hospital. Disruptions caused by COVID-19 resulted in the last five interviews being conducted via telephone.

The exploratory nature of this research meant a pre-developed “Interview Schedule” was loosely followed. The full list of questions is reported in Table 1 (Appendix). Occasionally, the order of questions was changed or the course of the interview adapted, to enable more in-depth exploration of topics spontaneously disclosed by patients.

All interview responses were confidential, data was anonymised and processed in accordance with General Data Protection Regulation 2016 (GDPR).

Demographic and patient medical notes were consulted to obtain medical information.

2.5. Ethical considerations

The potential risks to patients participating in this research were considered limited. However, it was recognised that patients may experience some distress if recalling difficult past events during the interview. In anticipation, it was agreed that researcher could consult the CHD Team and refer to appropriate services for support, if necessary.

2.6. Data analysis

A constructionist epistemological perspective stance was taken [30]. Constructivism is a research paradigm that proposes realities are man-made concepts, which are the creation of human interactions [31]. It does not consider there to be one “true” reality, rather reality is highly individual, subjective and context-dependent. Elements are influenced by human perception, society and culture. It is a pragmatic and relativistic approach, which encompasses a collection of views, rather than a single doctrine.

Analysis of data was conducted, in relation to the research question, using thematic analysis. The analysis was inductive in nature; thus, the data itself drove the structure of the analysis, rather than pre-existing theories or frameworks [32]. This comprehensive approach promotes completeness, rather than convergence, allowing in-depth exploration of participants’ perceptions, beliefs and experiences. When new themes were no longer emerging, data saturation was felt to be reached and recruitment of participants was drawn to a close [32].

These methods were chosen to optimise validity and followed the six phase guidelines described by Braun & Clarke (2006) [33].

3. Results

3.1. LIP

Thirty-three patients, 20 male and 13 females, aged 18–70 years were approached to participate in the LIP. 12 Fontan patients declined to participate. In total, 21 patients accepted and were recruited into the three-month LIP. The breakdown of CHD diagnoses of these comprised one Fontan, eight Tetralogy of Fallot, three Coarctation of the aorta, seven Atrial Septal Defect and two ccTGA (congenitally corrected transposition of the great arteries). Of these 21 patients, 11 male and 10 females, aged 21–70 years (mean = 38.25) three completed the full LIP. Of the remaining 18 patients, two dropped out after their second visit and 16 after their initial visit.

3.2. Interviews

Twelve patients, seven men and five women, aged 17–63 years (mean = 39, SD = 16.9) were interviewed; seven in Group 1 and five in Group 2 (Appendix - Table A2). Analysis of Group 1 transcripts resulted in identification of three main themes and four subthemes (Appendix - Fig. 1). Analysis of Group 2 transcripts resulted in identification of a further four themes and two corresponding subthemes (Appendix - Fig. 2). Each theme and corresponding subtheme are discussed in turn, with excerpts from participants’ transcripts included in Appendix – Table 3.

3.3. Group 1 themes

Expectations of Lifestyle Intervention Programme and Intentions to engage

Patients shared clear expectations of improved fitness and health, with great intentions to follow the personalised programme to make lifestyle changes to improve their health. Within this theme, two sub-themes more clearly depict the key issues that were identified:

Expectations of Programme

Patients spoke animatedly about expecting to improve their level of fitness and long-term health. They ascribed this to the support they would receive by participating in the LIP. Additionally, patients were keen to engage with the LIP in order to learn more about their condition and the lifestyle choices they should be making, regarding diet and safe physical activity, to improve their health.

Intentions to Adhere to Programme and Implement Personalised Lifestyle Plan

Patients spoke determinedly about adhering to the LIP, if they were invited to participate. They described high motivation and particular interest in the personalised nature of the programme, with individualised feedback and lifestyle plans. Patients conveyed keenness to change their behaviour and strong intentions to follow the programme.

Views about Online Support for Lifestyle Intervention Programme

Patients expressed clear views about whether or not they would like online, remote support if they participated in the LIP. Within this theme, the following two subthemes depict the recurring topics:

Preference for Online Support and Resources

Around three-quarters of patients clearly expressed preference for communication to be online and for support to be delivered remotely. A dislike of attending hospital and ease of being able to access support remotely from home, without having to travel, were stipulated as reasons for preferring online support. Communication in the form of emails was also popular. Patients spoke of wanting the opportunity to ask questions as and when they arose, rather than waiting for their next appointment and risk losing motivation in the meantime. Importantly, patients also expressed desire to receive more frequent, immediate feedback than just at follow-up hospital appointments.

The concept of a specifically-designed App became a prominent topic, with many patients welcoming the idea. Most were particularly interested in its potential to comprise useful resources; for example, educational items, exercise regimes and recipes.

Dislike of Technology

Contrastingly, other patients expressed clear dislike of online communication and technology; stating the impersonal and generic nature as reasoning. They also reported feeling overwhelmed by technology or certain Apps, thus these patients specified a keen preference for receiving face-to-face support and feedback. They felt this would make them more likely establish a rapport with the team, which would help them engage better with the programme.
Patient Anxieties about exercise damaging their heart

Many patients held strong health beliefs about exercise damaging their heart. Consequently, they spoke of avoidance, or engagement in more gentle forms of exercise, to appease this fear. Significantly, these accounts demonstrate the potential value of LIPs to increase patient understanding and knowledge, to help change these beliefs and break this barrier. The majority of these patients talked about being interested in the LIP, primarily to learn how to safely exercise without damaging their heart.

3.4. Group 2 themes

Insensitive Dietary Information

Patients expressed disappointment at not receiving more detailed feedback about diet plans, nor the support they needed to implement dietary changes. Reflecting back, patients regarded the LIP to be focused on physical activity, rather than diet. Overall, patients highlighted a need to receive more guidance about what constitutes good nutrition, especially in relation to their personal condition, and how best to implement positive dietary changes.

Brilliant Intentions Marred by barriers

Patients spoke of great intentions to follow their plans and make positive changes but there was always something that prevented them from following through their intentions. Within this theme, two sub-themes were identified:

Great Intentions to Make Lifestyle Changes

All patients expressed good intentions to implement plans and make changes to their daily lives. However, they struggled to follow their intentions through and often did not translate them into actual behaviour.

Barriers to Behaviour Change

Equally, every patient acknowledged that barriers prevented them from implementing their individualised lifestyle plans and engaging in positive health behaviour change. Most frequently, patients reported a lack of time. Others felt unable to translate their intentions into behaviour due to fatigue or psychological barriers. Some patients identified limited knowledge or lack of understanding of the rationale behind why it was so important to make certain changes to their behaviour.

Pertinence of Plans to patients

Some patients expressed struggles with trying to follow their lifestyle plans and believed they were not always well-designed for them. They described feeling exercise regimens were not appropriate for their level of fitness and goals they were advised to work towards were not pertinent or important to them.

Conversely, other patients described how the programme was tailored, and goals specifically-refined, to be pertinent to them. These experiences were commonly spoken of with reference to increased motivation to adhere to the LIP.

Positive Patient Experiences and Outcomes

Most patients spoke positively of their experiences of participating in the LIP. They shared examples of how beneficial they found the programme and the positive lifestyle changes they believe it enabled them to make.

4. Discussion

A wealth of literature supports the benefits associated with physical activity, good nutrition and stress management. Given that a lifestyle comprising well-balanced nutrition and moderate physical activity promotes the accrual of health benefits, early intervention is key. The evidence base already recognises efficacious LIPs as cost-effective interventions for producing physical and mental health benefits, and reducing mortality in other chronic conditions [34,35]. This is especially pertinent for patients with CHD, in whom poor lifestyle choices compound the risk of developing co-morbidities and life-threatening complications related to their condition.

This study provided greater understanding of determinants of adherence to LIP in patients with CHD. The qualitative nature of this research enabled in-depth exploration of patients' experiences and views. Six key findings, which were identified from the emerging themes and subsequently used to inform recommendations for development of CHD LIP, these include:

Expansion of educational component
Need for health psychology and dietetic support
Increased focus on barriers to adherence and positive behaviour change
More individualised, pertinent SMART goal-setting
Implementation of techniques aimed to improve self-efficacy and maintain motivation
Development of specifically-designed App

Rich and detailed feedback from patients provided testimony for the abundance of benefits accrued from participating in the LIP, which are not always reflected by objective outcome measures. Poor patient adherence did not reflect the potential value of lifestyle intervention, rather it highlighted the need for difficulties and barriers to adherence to be better understood and addressed. As recognised by MRC Guidance on the development and evaluation of complex interventions, a lack of desired impact may simply be a reflection of implementation “teething problems”, rather than genuine intervention ineffectiveness [36].

Some patients highlighted desire for more information; to develop their understanding and knowledge. This was said with regard to nutrition and the beneficial impact of physical activity on the heart. Beliefs that exercise could damage the heart resulted in anxiety and avoidance of appropriate physical activity in some patients. However, this anxiety and perceived severity increased patients’ interest in participating in the LIP. Similarly, more nutritional education and dietary guidance by specialists in this field might address feedback from patients that nutritional information was insufficient to enable them to elicit dietary change. Overall, findings are congruent with previous research, which suggests that adherence is not just related to perceived barriers but how patients weigh these up against perceived benefits [15,37]. These results suggest the need for more education in order for patients to better understand the beneficial effects of appropriate physical activity and to tackle anxieties or misconceptions [38-40].

Given that the 12 patients who declined to participate in the LIP were some of the most complex CHD, those with Fontan circulation, more education may be especially pertinent. These patients have clearly been demonstrated to be least likely to participate in a LIP, despite the benefits associated with increased physical activity and engagement in positive health behaviour change [3,6,41].

Although data was analysed using an inductive approach, which included reflexive practice to minimise bias and avoid influence from pre-conceived knowledge, a common theme fitted well within Theory of Planned Behaviour [11]: patients have good intention to follow their individualised plans and change their behaviour but barriers, perceived and real, prevented them from doing so. These findings are consistent with what has been previously documented [19,42] and highlight the “intention-behaviour gap”. This problem is well-recognised within the
field of health psychology. Health psychologists are well-trained to help patients identify and address determinants of adherence and teach techniques that enable translation of good intentions into actual behaviour.

The importance of effectively integrating psychological services into wider healthcare service including cardiology is becoming increasingly recognised [43,44]. Thus, there is tremendous scope for health psychologists within CHD LIPs to provide the multi-faceted support patients need to better engage in positive health behaviour change.

Health psychologists are well-positioned to address concurrent mental health issues, which often further impede adherence. Different techniques, such as Acceptance and Commitment Therapy, Cognitive Behavioural Therapy and Motivational Interviewing, can elicit behaviour change by supporting individuals to explore and resolve ambivalence. Results from this study supported previous research, which found patients might benefit from being taught stress-reducing practices within the LIP; such as breathing relaxation exercises and mindfulness [45].

When it comes to optimising LIP design, COM-B is an integrated model that maps intervention techniques onto theoretical components [22,46]. Behavioural taxonomies, including the Behaviour Change Wheel, offer the framework upon which LIPs can be effectively developed. It provides guidance on how to identify specific Behaviour Change Techniques, and modes of intervention delivery, which are most likely to promote behaviour change. A 2015 review suggested 89% of LIPs, like the CHD LIP pertaining to this qualitative study, are not theory-based [47]. Linking theory with intervention design is consistent with MRC guidance suggesting patients might benefit from more theory-based understanding of behaviour being incorporated into CHD LIP [36,48].

Looking to the future, it is important patients can develop confidence; to communicate difficulties that need addressing and work collaboratively with healthcare professionals towards appropriately-tailored, pertinent SMART goals alongside increased patient self-efficacy [49, 50]. Initial face-to-face contact can help best engage patients and contextualise the work. This study found initial adherence, and early significant results, were associated with behaviour change; supporting previous evidence that LIPs benefit from a “front heavy” design [5,51]. Therefore, patients benefit from face-to-face appointments supported by remote monitoring and online correspondence to sustain adherence; which may need to continue for six months to a year [51].

Findings from this study support the potential for online resources to make a valuable contribution to the repertoire of tools available to time-poor healthcare professionals. Whilst a small number of patients expressed a dislike of technology, most patients voiced preference for online support; in the form of email communication and specifically-designed Apps to provide more immediate feedback and the ability to track their own progress. Motivating affirmations, and messages about the benefits of engaging in positive behaviour change, need repeating over and over again, as behaviour change occurs over time [51]. Evidence is growing for the efficacy of Apps to promote, and sustain, positive behaviour change by cultivating self-monitoring and motivation [52]. Virtual support can help reduce the number of hospital appointments. Necessity for online support and virtual options may be greater than ever in this unprecedented time of COVID-19. The NHS Long-Term Plan proposed digital-first primary care to be available to most by 2023/24 [33], though effective remote care has quickly become essential during this unprecedented time of Covid-19.

4.1. Strengths and limitations

The qualitative nature of this study provided a unique opportunity to explore the clinical challenge of achieving positive health behaviour change, from patients’ perspectives thus contributing to inform the design of more efficacious LIPs. Other strengths include the equal representation of genders; 42% male to 58% female participants, and the richness of results provided by the in-depth interviews, which enhance generalisability of findings.

A critique would be the small number of participants. However, qualitative research usually comprises smaller sample sizes, in order to achieve deep and richly-textured understanding of patients’ feedback [33]. A small number of participants in the original pilot study meant only a small sample could be approached. Nevertheless, based on a detailed review of current literature and taking into account study parameters, the sample was still considered large enough to enable the unfolding of a richly-textured understanding of patients’ expectations and experiences [54]. In addition, data saturation was felt to be reached, as no new themes emerged from later interviews [33].

Secondly, generalisability of results was limited by certain demographics. Patients included in the study were generally young, which may explain fewer co-morbidities. 92% of patients self-identified as White British. The impact of physical activity and diet on well-being is cross-culturally ubiquitous, however, influencing factors are recognised to differ between cultures. Therefore, future studies could be enriched by including larger, more diverse samples.

Lastly, there is the possibility of recall bias, as anywhere from two to seven months had passed between when the interviews were conducted and the CHD LIP.

4.2. Future clinical implications

Implications of findings from this qualitative research can be applied to development of the CHD LIP and the broader field of health psychology. For an effective LIP, a multidisciplinary approach is needed with active involvement of a health psychologist and dietitian, in addition to the cardiology research team and exercise physiologist. Additionally, results support the incorporation of more technology, such as a specifically-designed App that could provide patients with educational resources and online support. Constant affirming messages and email communication with the LIP team also plays a key role in maintaining patients’ adherence.

Patients with learning difficulties are least likely to have access to the LIP. Such patients often have poorer health knowledge and are amongst those at greatest risk of developing complications and co-morbidities, particularly obesity. Interventions for these patients will be more complex and require the need to support the whole family, or carers, as they are often responsible for patients’ diet and physical activity levels.

Lastly, further studies would benefit from including adolescents, as this is a key developmental stage when lifestyle is formed and bad habits can make positive behaviour change more difficult to achieve.

4.3. Wider clinical implications

The potential role of LIP to improve patient’s quality of life, sympotmatology and prognosis, whilst reducing high long-term healthcare costs associated with CHD, needs better recognition by NHS decision makers and budget holders. Results from this study may inform the design of subsequent RCTs, given that CHD LIPs are in alignment with the NHS Long-Term Plan.

Looking to the future, the design of more efficacious LIPs would benefit from studies exploring psychological metrics and relationships between adherence and mediating variables; such as motivation towards lifestyle changes, self-efficacy, perceived susceptibility and patient knowledge. Longitudinal research, comprising experimental studies that include quantitative measures, offers scope to measure changes in mediating factors pre- and post-intervention, alongside the implementation of health behaviours. This would increase understanding of specific BCTs, which prove most effective at changing beliefs that pertain to particular health behaviours. Lastly, further research with meta-analyses, could help identify types of intervention, and modes of delivery, which are most efficacious at addressing determinants of poor adherence and promoting positive health behaviour change.
5. Conclusions

This study presents positive initial findings supporting scope for specifically-designed CHD LIPs to make a valuable addition to future clinical practice. It provides deeper understanding of the determinants of adherence to LIPs and positive health behaviour change. The powerful impact of barriers to behaviour change was demonstrated, highlighting the need for more specialised health psychology support, education and rigorous follow-up of patients, as well as the need for programmes to be individually-tailored and multi-faceted.

Psychological theories, namely HBM, TPB and COM-B, helped contextualise this work and enabled discussion around the additional support more complex patients might require.

Contributors

All authors attributed to the conception, design, critical revision and final approval of this manuscript.

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Ethics approval

The Pilot Study was conducted in compliance with the principles of the Declaration of Helsinki, the principles of GCP and any applicable regulatory requirements.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A

Table A.1

<table>
<thead>
<tr>
<th>Interview Questions</th>
<th>Group 1 Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) What information would you hope to receive if you were to participate in a Lifestyle Intervention Programme focussing on diet, physical activity and stress management?</td>
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<tr>
<td>2) What would your expectations be about a Lifestyle Intervention Programme specifically-designed for Congenital Heart Disease?</td>
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<tr>
<td>3) What, if anything, would you be anxious about if you were to participate in such a programme?</td>
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<tr>
<td>4) What would you hope to achieve by participating in a Lifestyle Intervention Programme?</td>
<td></td>
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<tr>
<td>5) Can you see any potential obstacles to adhering to a personalised lifestyle plan? If so, what might you need in order to follow your plan and complete the full programme?</td>
<td></td>
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<tr>
<td>6) Is there anything else you would like to add before we finish?</td>
<td></td>
</tr>
<tr>
<td>Group 2 Questions</td>
<td></td>
</tr>
<tr>
<td>1) What elements were particularly good about the Lifestyle Intervention Programme?</td>
<td></td>
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<tr>
<td>2) What was not so helpful about the programme or what do you wish could have been done differently?</td>
<td></td>
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<tr>
<td>3) Did you feel the aims of the programme were sufficiently well-explained to you?</td>
<td></td>
</tr>
<tr>
<td>4) Did you feel the programme was appropriately tailored to you?</td>
<td></td>
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<tr>
<td>5) Did you feel the goals were pertinent to you?</td>
<td></td>
</tr>
<tr>
<td>6) Did you perceive your goals to be in-line with the goals of the team delivering the programme?</td>
<td></td>
</tr>
<tr>
<td>7) Did you feel adequately supported by the team delivering the programme?</td>
<td></td>
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<tr>
<td>8) Did you find it difficult to adhere to the programme? If so, can you describe what you felt were the main barriers that prevented you from adhering to your plan?</td>
<td></td>
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<tr>
<td>9) Did you feel anxiety about participating in the programme? If so, can you identify anything that might have helped reduce your anxiety?</td>
<td></td>
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<tr>
<td>7) Was the programme as you expected, or hoped it would be? If not, how did it differ?</td>
<td></td>
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<tr>
<td>8) Did you achieve what you hoped to achieve? If not, what did you feel prevented you being able to and what might have helped address this?</td>
<td></td>
</tr>
<tr>
<td>9) Is there anything else that you think is important to share with me before we finish?</td>
<td></td>
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Table A.2

<table>
<thead>
<tr>
<th>Interview ID</th>
<th>Gender</th>
<th>Age</th>
<th>Congenital Heart Disease Diagnosis</th>
<th>Pre-existing Co-morbidities</th>
<th>BMI</th>
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<td>Group 1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>1</td>
<td>Female</td>
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<td>Perimembranous Ventricular Septal Defect</td>
<td>Migraines</td>
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<td>Atrioventricular Septal Defect</td>
<td>Learning Difficulties</td>
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<td>Pulmonary Valve Stenosis</td>
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<td>Hyper tension</td>
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<td>Pulmonary Atresia – Fontan</td>
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<td>Female</td>
<td>63</td>
<td>Pulmonary Valve Stenosis</td>
<td>None</td>
<td>26.4</td>
</tr>
</tbody>
</table>

(continued on next column)
<table>
<thead>
<tr>
<th>Interview ID</th>
<th>Gender</th>
<th>Age</th>
<th>Congenital Heart Disease</th>
<th>Pre-existing Co-morbidities</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6</td>
<td>Male</td>
<td>17</td>
<td>Moderate Aortic Stenosis and Regurgitation</td>
<td>Hypercholesterolaemia Migraines</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Male</td>
<td>23</td>
<td>Atrial Septal Defect</td>
<td>None</td>
</tr>
<tr>
<td>Group 2</td>
<td>8</td>
<td>Male</td>
<td>49</td>
<td>Pulmonary Valve Stenosis. Patent Foramen Ovale</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Male</td>
<td>41</td>
<td>Absent Pulmonary Valve</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Male</td>
<td>42</td>
<td>Aortic Valve Stenosis</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Female</td>
<td>57</td>
<td>Ventricular Septal Defect</td>
<td>Recent Hip Replacement</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>Male</td>
<td>37</td>
<td>Transposition of the Great Arteries</td>
<td>None</td>
</tr>
</tbody>
</table>

![Figure A.1](image1.png)

**Figure A.1.** Final thematic mind map, showing final three main themes, and four subthemes, for group 1 patient interviews (n = 7).

![Figure A.2](image2.png)

**Figure A.2.** Final thematic mind map, showing final four main themes, and two subthemes, for group 2 patient interviews (n = 5).

### Table A.3

#### Sample of Coding Manual.

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Positive Example</th>
<th>Negative Example</th>
<th>Exemptions / Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient beliefs that exercise will further damage their heart</td>
<td>This describes beliefs participants hold about exercise damaging their heart further</td>
<td>“I am deliberately not engaging in exercise, as I fear my heart could not cope” (Participant 7)</td>
<td>“I worry about not doing enough exercise, in case this damages my heart further” (Participant 1)</td>
<td>This does not describe beliefs participants hold about how damaged their heart is as a result of their Congenital Heart Disease</td>
</tr>
<tr>
<td>Congenital Heart Disease knowledge and understanding</td>
<td>This relates to a participant's level of knowledge and understanding of Congenital Heart Disease</td>
<td>“I mean, I understand the rationale behind not smoking” (Participant 10)</td>
<td>“I did not know that exercise could actually benefit my heart” (Participant 9)</td>
<td>This does not relate to a participant's level of general knowledge</td>
</tr>
<tr>
<td>Appropriateness of exercise plan</td>
<td>This refers to how appropriate participants considered their exercise plan to be for them</td>
<td>“very quickly my exercise plan was perfectly suited to me. It was primarily focussed on cycling, which was brilliant!” (Participant 8)</td>
<td>“The Programme was a good idea but I believe it was not tuned to me” (Participant 9)</td>
<td>This does not refer to whether participants liked their exercise plan</td>
</tr>
</tbody>
</table>

(continued on next column)
I do remember being warned about the effects of alcohol
programme and, with the support of the physiotherapist,
do not remember diets being so unhealthy?

I was so grateful to have the opportunity to take part in the

None of this would have been possible without the

from 92kg. I now cycle

before participating in the programme, I felt overwhelmed
by the prospect of even trying to start getting fitter and
did not think I had time.

I was grateful to receive a little

from Land’s End to John O’Groats, after I turn fifty next year.

it would follow the recommended advice. I am
determined to get healthier.” [P6; male, 17, BMI 23.6]

I would be particularly interested in advice regarding physical activity and how to re-build
my fitness. Consequently, I feel confident I would follow the recommended advice. I am
determined to get healthier.” [P6; male, 17, BMI 23.6]

I would like to make changes that could help my heart but do not know how to. I would be
very interested in receiving a personalised plan and feel motivated that I would follow it”
[P7; male, 24, BMI 23.6]

I would love to receive personalised feedback about diet and physical activity” [P4; female,
22, BMI 22]

I would be grateful information about what I should be eating. I would expect to be told
what changes I need to make, especially to my diet.” [P7; male, 24, BMI 21.4]

It would be good for me and might help me take more responsibility for my health. I don’t
know much about what I should be eating or what exercise I should be doing!” [P5; female,
63, BMI 26.4]

It would be nice to reduce my chances of having further problems with my heart, if I could be
helped to make positive changes.” [P3; female, 70, BMI 25.1]

It would be good for me and might help me take more responsibility for my health. I don’t
know much about what I should be eating or what exercise I should be doing!” [P5; female,
63, BMI 26.4]

I would be grateful information about what I should be eating. I would expect to be told
what changes I need to make, especially to my diet.” [P7; male, 24, BMI 21.4]

It would be good for me and might help me take more responsibility for my health. I don’t
know much about what I should be eating or what exercise I should be doing!” [P5; female,
63, BMI 26.4]

I was grateful to receive a little

I would be particularly interested in advice regarding physical activity and how to re-build
my fitness. Consequently, I feel confident I would follow the recommended advice. I am
determined to get healthier.” [P6; male, 17, BMI 23.6]

I would love to make changes that could help my heart but do not know how to. I would be
very interested in receiving a personalised plan and feel motivated that I would follow it”
[P7; male, 24, BMI 23.6]

I would like to make changes that could help my heart but do not know how to. I would be
very interested in receiving a personalised plan and feel motivated that I would follow it”
[P7; male, 24, BMI 23.6]

I would love to receive personalised feedback about diet and physical activity” [P4; female,
22, BMI 22]

It would be nice to reduce my chances of having further problems with my heart, if I could be
helped to make positive changes.” [P3; female, 70, BMI 25.1]

It would be good for me and might help me take more responsibility for my health. I don’t
know much about what I should be eating or what exercise I should be doing!” [P5; female,
63, BMI 26.4]
carried out remotely, via an App or something.” [P6; male, 17, BMI 23.6]

“I would appreciate the facility to email my questions in between sessions … and I’d like continual feedback about my progress” [P5; female, 63, BMI 26.4]

“An App would be great, especially if I could learn things from it and if there were things like healthy recipes” [P1; female, 22, BMI 28.9]

“I’d love to have an App that included recipe or workout suggestions!” [P4; female, 22, BMI 22]

**Group 2 Insufficient Dietary Information**

“Without knowing more, I am very concerned about pushing myself too hard when exercising, especially with swimming.” [P6; male, 17, BMI 23.6]

“I am deliberately not engaging in exercise, as I fear my heart could not cope. I would like to learn more about what would help my heart because, unless I am told otherwise, I am anxious about doing any exercise other than walking.” [P7; male, 24, BMI 21.4]

**Patient Anxieties about Exercise**

“Without knowing more, I am very concerned about pushing myself too hard when exercising, especially with swimming.” [P6; male, 17, BMI 23.6]

“I am deliberately not engaging in exercise, as I fear my heart could not cope. I would like to learn more about what would help my heart because, unless I am told otherwise, I am anxious about doing any exercise other than walking.” [P7; male, 24, BMI 21.4]

**Barriers to Behaviour Change**

“I think I was given a vague diet at the start but nothing after that, like the advice I needed about how to actually implement it.” [P9; male, 41, BMI 24]

“I would have appreciated much more detailed dietary guidance. I was disappointed, as advice was lacking!” [P11; female, 57, BMI 30.2]

“I was given no dietary advice.” [P10; male, 42, BMI 24.5]

“I felt the benefit when I did practice breathing mindfully and do my exercises, so I always intended to fit them in every day but never did.” [P10; male, 42, BMI 24.5]

“I would have these great intentions and then every night, I would get into bed and think… oh no, I haven’t done my exercises again!” [P11; female, 57, BMI 30.2]

“I always planned to do my exercises tomorrow but something always prevented me from doing so.” [P10; male, 42, BMI 24.5]

“I already had to get up at 5am to fit everything in, so I didn’t have time to implement much exercise.” [P10; male, 42, BMI 24.5]

“I had so much work on, I just didn’t have time!” [P12; male, 37, BMI 22.1]

“I struggled with fatigue at the time and lacked the energy to follow my plan.” [P10; male, 42, BMI 24.5]

“I felt too exhausted after trying to keep up with my exercises for a few weeks.” [P11; female, 57, BMI 30.2]

“I didn’t have much confidence. I wanted to do things well but couldn’t manage my exercises, which was stressful!” [P11; female, 57, BMI 30.2]

“I had a lot of anxiety and issues to deal with, which got in the way of me following my plan.” [P10; male, 42, BMI 24.5]

“I didn’t understand how the exercises I was given would help my heart” [P9; male, 41, BMI 24]

“I just couldn’t see how these changes would benefit my heart!” [P10; male, 42, BMI 24.5]

“The Programme was a good idea but I believe it wasn’t tuned to me. My usual cycle ride was more physically challenging, so the plan felt demotivating, as it did not help me push myself towards new goals.” [P9; male, 41, BMI 24]

“I was excited about receiving personalised plans and support to implement it but I struggled with fatigue at the time, so felt the exercises were inappropriate. They always wiped me out and I never got to a point where they began to feel easier.” [P10; male, 42, BMI 24.5]

“I couldn’t manage the plan I was given and I felt the goals that were set didn’t really address what was important to me.” [P11; female, 57, BMI 30.2]

“The physiotherapist worked closely with me to personalise my programme and help me set realistic, achievable goals that were important to me. I then felt motivated to work towards them!” [P8; male, 49, BMI 25.9]

“….because I was struggling with such high anxiety, I was offered additional support from a psychologist, which was extremely helpful! I found the Mindfulness training beneficial and these sessions helped motivate me to stick to my plan.” [P10; male, 42, BMI 24.5]

“At first, I felt stressed because I couldn’t do the exercises. However, when I shared this with the Physiotherapist, he was extremely supportive and changed me onto a ‘points system’, which suited me far better as I could have a day off once I achieved my target!” [P11; female, 57, BMI 30.2]

“Positive Patient Experiences and Outcomes”

“The programme changed my life. I felt overwhelmed by the prospect of even trying to start getting fitter and didn’t think I had time. I was so grateful for the opportunity to participate in the programme and, with the support of the physiotherapist, feel I achieved all my goals. I got my weight down to 82 kg, from 92 kg. I now cycle five times a week and plan to race from Land’s End to John O’Groats, after I turn fifty next year.” [P8; male, 49, BMI 25.9]

“I liked being explained to about why improving my heart rate was so important for my condition. It helped motivate me to stick to my plan and make changes.” [P12; male, 37, BMI 22.1]

“I hoped the programme would help me feel better and it did. I still use the stress management techniques I was taught when I am symptomatic; to reduce my anxiety, focus my mind and help me better implement my breathing exercises.” [P10; male, 42, BMI 24.5]

“Great Intentions to Make Lifestyle Changes”

“I felt the benefit when I did practice breathing mindfully and do my exercises, so I always intended to fit them in every day but never did.” [P10; male, 42, BMI 24.5]

“I would have these great intentions and then every night, I would get into bed and think… oh no, I haven’t done my exercises again!” [P11; female, 57, BMI 30.2]

“I always planned to do my exercises tomorrow but something always prevented me from doing so.” [P10; male, 42, BMI 24.5]

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