Title: A feasibility hybrid randomised controlled trial of a volunteer 'Health Champions' intervention supporting people with serious mental illness to manage their physical health

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Abstract

Background

People with severe mental illness (SMI) have worse physical health than the general population. There is evidence that support from volunteers can help the mental health of people with SMI but little evidence regarding the support they can give for physical health.

Aims

To evaluate the feasibility of an intervention where volunteer ‘Health Champions’ support people with SMI in managing their physical health.

Method

A feasibility hybrid randomised controlled trial conducted in Mental Health Teams with people with SMI. Volunteers delivered the ‘Health Champions’ intervention. We collected data on the feasibility of delivering the intervention, and clinical and cost effectiveness.

Participants were randomised by a statistician independent of the research team to either having a Health Champion or treatment as usual. Blinding was not done.

Results

48 participants were recruited, 27 to intervention group and 21 to control group. Data was analysed for 34 participants. No changes were found in clinical effectiveness for either group. Implementation outcomes measures showed high acceptability, feasibility and appropriateness but with low response rates. No adverse events were identified in either group. Interviews with participants found they identified changes they had made to their physical health. The cost of implementing the intervention was £312 per participant.

Conclusions

The Health Champion intervention was feasible to implement, but the implementation of the study measures was problematic. Participants found the intervention acceptable, feasible and appropriate and it led them to make changes in their physical health. A larger trial is recommended, with tailored implementation outcome measures.

Trial registration*:* ClinicalTrials.gov, registration no: NCT04124744

Background

People diagnosed with a serious mental illness (SMI), such as schizophrenia or bipolar disorder, experience inequalities in their physical health compared to the general population (1, 2). This includes having multiple long-term conditions and shorter life expectancy of approximately 10 years (3). The underlying causes of this are complex and multi-faceted, located at individual, service organisation, and societal levels (4). Approaches to address these health inequalities at the individual level have included interventions to support people with SMI to lose weight (5), be more physically active (6), and manage specific illnesses (e.g. diabetes), with varying levels of success. At a service organisation level, there is evidence that people with SMI report challenges in navigating complex health care services (7), and can also be impacted by 'diagnostic overshadowing,' whereby health care professionals attribute physical health concerns to their mental illness (8). At the societal level, stigma and discrimination towards people with SMI can negatively impact on their day-to-day living and experiences, including in interactions with health care services and professionals (9).

One promising potential approach that could help individuals with SMI manage their physical health is the use of volunteer support. Volunteers are recognised as providing value in healthcare settings (10) and are explicitly mentioned in national policy such the NHS Long Term Plan in England (11) and the Volunteering Taskforce report (12). Volunteer provision of individual support for people with SMI improves mental health, increases social contacts, and reduces loneliness and social isolation among those with SMI (13) (14) (15, 16). This type of volunteering also benefits the volunteers themselves, through feeling useful and acquiring new skills (16). To date, we know of no studies that have evaluated whether it is feasible to deliver a volunteer intervention to support the physical health of people with SMI, and the potential health impacts such an intervention may have.

Aims of the study

This study aimed to evaluate the feasibility and acceptability of an intervention where trained volunteer 'Health Champions' support people with SMI in managing their physical health, compared to treatment as usual. We were interested in the feasibility in terms of being able to recruit service users and Health Champions, and whether both groups engaged with the intervention. We did not pre-define the numbers needed to progress to a larger trial. We collected data on implementation challenges, and clinical and economic metrics to inform a potential larger scale trial evaluation.

Methods

Study Design

This was a feasibility hybrid randomised controlled trial (RCT), which evaluated both clinical and implementation outcome measures, and analysed costs but was not

powered to assess changes in clinical, implementation, or cost effectiveness outcomes (17). Detailed methods and design were reported in the published study protocol (17).

Setting

This study took place in Community Mental Health Teams (CMHTs) in the South London and Maudsley NHS Foundation Trust (thereafter, the 'Trust') in London, UK. The Trust provides secondary mental health services for four London boroughs: Croydon, Lambeth, Lewisham and Southwark.

We collected data from both service user participants and volunteer Health Champions. For clarity, we refer to service user participants as 'service users' and volunteer Health Champions as 'Health Champions'.

Service user recruitment

Service users were recruited directly from CMHTs with staff in the teams identifying people who may be eligible; or by using the Trust's Consent for Contact (C4C) service (https://slam.nhs.uk/consent-for-contact/) to identify people who had previously consented to be approached by researchers to take part in research projects. A baseline assessment which included the clinical outcomes (see relevant section below) and questions about why the person wanted to take part in the study was then conducted by telephone. Following this assessment, service users were randomised to either the intervention or control group.

Inclusion criteria for service users:

- 18 years and above.
- Diagnosis of an SMI including schizophrenia, bipolar disorder, schizoaffective disorder, delusional, and other non-mood psychotic disorders and major depression.
- Wanting to make changes to their physical health.
- Capacity to give written informed consent to take part in the study in the English language.
- Able to provide a named care coordinator or other point of contact in the CMHT reachable in the event of a health crisis.

Health Champions recruitment

Health Champions were recruited from existing Trust volunteers in accordance with Trust policies.

Health Champion eligibility criteria:

- Existing Trust volunteer who had completed Trust Volunteer training.
- 18 years and above.
- Disclosure and Barring Service (DBS) checked and cleared.
- Able to attend the additional training relevant to the study

- Willing to commit one hour per week (average) for up to 9 months for the duration of the study.

The intervention

Service users were matched with a volunteer 'Health Champion' by a volunteer coordinator. Matching was based on geographical area and interests. We tried to meet any preferences service users had in terms of age, gender, and ethnicity. They were paired for nine months with an expectation of meeting hourly once a week, either face-to-face or remotely.

The Health Champion's role was to support the service user with the physical health goals that were important to them. In the first session the service user was encouraged to let the Health Champion know what these goals were. The support that the Health Champion would provide was then agreed between the pair, and could include discussing issues and challenges that the service user was facing, giving advice, and participating in activities together. We did not prescribe what the goals could be, or how the support was given. Both service users and Health Champions were given a journal to complete if they wished to keep track of their progress.

Study recruitment started in September 2020 and ended in May 2021. It was initially designed to take place face-to-face, but adaptations were made to allow remote meetings in line with COVID-19 restrictions at the time of the study. Thus, initially the pairs met remotely but were able to meet face-to-face when physical distancing restrictions in the UK were lifted and if/when both parties were happy to do so.

Health Champions support

Health Champions were supported by the volunteer coordinator and research team throughout the study; this included initial training on the role, monthly group supervision and individual support as needed.

Control group

Service users in the control group received treatment as usual from their CMHT regarding the management of their physical health, which could include physical health checks as mandated by NHS England (NHS England 2019) and support from a care coordinator. Service users in the control group received a copy of a workbook on managing physical health which had been developed in the Trust which includes sections on how people can look after their physical health, and a copy of the journal given to service users in the intervention group (appendix 2).

Randomisation

Randomisation was conducted by a statistician at King's College London, independent of the study and blinded to allocation and control group. The randomisation system randomly sequenced the order of the service users and entered them into the study stratifying by local borough of residence. A random

number generator was used to assign service users to the intervention or the control group. The randomised numbers were put into sealed envelopes in lists for each borough. After a baseline assessment had been completed, the researcher opened the next envelope in the list for that borough to reveal which group the service user was assigned to. The research team was not aware of the allocation until they opened this envelope.

Sample size

As this was a feasibility RCT, a power calculation to calculate sample size was not appropriate (18). Considering the study resources and nature of the study design in that this was a feasibility study, we aimed for a sample size of 100 service user participants: 50 in the intervention group and 50 in the control group. This number is in line with recommendations for feasibility studies from Lancaster et al (19) and Sim and Lewis (20).

Data collection

Service users in both groups were asked to complete baseline and follow up assessments, at the end of nine months study duration. Service users were reimbursed £10 for their time at each assessment. At follow-up, service users in the intervention group and Health Champions were also invited to take part in an interview about their experiences.

Ethical approval

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2013. All procedures involving human subjects/patients were approved by Brent Research Ethics Committee, approval number: 20/LO/0214.

Clinical Effectiveness Measures

Primary outcome: Quality of Life

The primary clinical effectiveness outcome of interest was Quality of Life measured using the EQ-5D-5L which measures five domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression using five-point scales [20].

Secondary clinical outcomes

1. Self-management, using the 10-item Patient Activation Measure (21) raw scores are summed and transformed to 0-100 metric (0 = lowest activation level, 100 = highest)
2. Mental Health related Quality of Life, using the 10-item Recovering Quality of Life (ReQoL) measure (22), scores range from 0 to 40, where 0 indicates poorest quality of life and 40 indicates the highest quality of life.
3. Treatment Burden, using the 10-item Multimorbidity Treatment Burden Questionnaire (23) which generates 4 categories of treatment burden by grouping scores greater than 0 into tertiles: no burden (score 0), low burden (score <10), medium burden (10-22), high burden (>=22).

4. Loneliness, using the six item De Jong Gierveld Loneliness Scale (24) scored from 0 to 6 with 0 being least lonely and 6 most lonely.
5. Self-reported use of physical health services and physical health screenings.
6. Socio demographic information including age, gender, ethnicity, educational level, living arrangements, employment status and relationship status at baseline.

Implementation Outcomes

Primary outcome: Acceptability

This was measured using the validated four item Acceptability of Intervention Measure (AIM) (25). Each item is scored on a 1–5 point scale; scores can range from 4 to 20, with higher scores indicating higher perceived acceptability.

Secondary implementation outcomes

Feasibility and Appropriateness were measured using the validated Feasibility of Interventions Measure (FIM) and the Intervention Appropriateness Measure (IAM) (25). Both are structured as per the AIM above; scores can range from 4 to 20 with higher scores indicating higher perceived feasibility or appropriateness.

Qualitative data collection

We also assessed acceptability, feasibility, appropriateness, fidelity, barriers and facilitators, and unintended consequences qualitatively by interviewing service users and Health Champions.

Health Economics Measures

Cost of implementing the intervention

A cost analysis was undertaken to identify the cost of the intervention. Key implementation activities and the time spent by staff on each were identified. Where data was not available assumptions were made regarding the time taken to undertake specific activity (e.g., administrative tasks). Staff time was valued using published unit costs (hourly rates) for staff specific NHS Agenda for Change band levels Unit Costs of Health and Social Care 2021 | PSSRU. Researcher time allocated to implementation activities was valued based on costings provided by the university employer. All staff costs include salaries, indirect employment costs and institutional overheads. Costs of equipment were included based on current market rates. These capital expenditures were annualised (assuming equipment lifetime of 3 years and discount rate of 3%): This enables equipment costs to be allocated to the period covered by the project (20 months).

Cost of wider health service utilisation

Wider health care service utilisation was measured using an adapted version of the patient self-report Adult Service Utilisation Schedule (AD-SUS);(26) administered by a researcher at baseline and at 9 months post-randomisation for both trial groups. Service users were asked to report retrospectively the number of contacts made with (i) GPs, (ii) hospital outpatient departments (any reason, mental health or acute setting), (iii) A&E (for any reason) and (iv) time spent admitted as an inpatient (for any reason). At baseline and at 9-months the AD-SUS recorded self-reported

contacts for the previous 6-month period. Published data on unit costs of health and social care and NHS Reference costs NHS England » 2021/22 National Cost Collection Data Publication were used to cost all reported service contacts.

Data analysis

Quantitative analysis
A descriptive analysis of baseline covariates and outcomes (both clinical and implementation measures) was carried out using absolute and relative frequencies (n and %) for categorical variables and medians and interquartile ranges (IQR) for continuous variables due to the small sample size (and the likely non-normal distributions). A description of the outcomes at 9-month follow-up was also performed. All these analyses were carried out for all participants and stratified by study group (i.e. Health Champions and control groups).
We assessed changes (before vs after) within each arm of the intervention and control condition on our clinical outcomes (e.g. EQ-5D-5L) with the use of linear regression models adjusting for baseline total score of EQ-5D-5L. Similar models were fitted for our secondary mental health outcomes.

Qualitative data collection and analysis
Semi-structured interviews were conducted using a topic guide developed by the research team, which asked about Health Champion's experiences of delivering the intervention and service users' experiences of taking part in the intervention, informed by the existing literature on implementation outcomes (see appendix 3). Interviews were conducted by JW and RM either on Microsoft Teams, by telephone or face-to-face. All interviews were digitally recorded and transcribed professionally. Interview transcripts were then checked by JW and RM for any errors and anonymised prior to qualitative data analysis.

A thematic analysis approach (27) was used to analyse and synthesise themes developed from the qualitative data. This involved initially coding interviews into themes, using both inductive and deductive coding to identify responses to specific interview questions covered by the topic guide and other aspects of participants' experiences. Service user and Health Champion interviews were coded first separately and then compared to look for similarities and differences in experiences within and between both groups. A coding framework was developed by JW, RM and MPC after they had read three initial transcripts. JW then coded all transcripts and shared this with MPC, RM and ES for further discussion and consensus on the themes. Any new themes were discussed as a group and the coding framework was modified accordingly.

Cost analysis

Intervention implementation costs are presented descriptively. We report the cost of specific implementation activities and their % contribution to overall cost of

implementation, total cost of implementation and total cost per Health Champion and per trial participant.

Health service utilisation costs were analysed descriptively. We present mean cost values and standard deviations for different categories of health care usage and total care utilisation cost by trial arm for the 6-month reporting period prior to interview at 9-months. Adjusted and unadjusted differences in mean total health care utilisation costs are also presented: adjustments were made for baseline cost and E5D-5L health state utility score differences. The statistical precision of adjusted differences is measured using 95% confidence intervals. Our analysis of health care use costs post-randomisation is carried out based on study participants who had complete data on service contacts (a complete case analysis).

All costs (intervention implementation and health care utilisation) are presented in 2020-21 values. Cost-analyses were undertaken in Microsoft Excel and Stata version 17.0.

Results

Service users

We recruited 48 service users of whom 27 were randomised to the intervention group and 21 to the control group. Recruitment took place from August 2020 to September 2021 and follow-up ended in June 2022. The socio-demographic characteristics of the service users at baseline are summarised in Table 1. There were no significant differences in any of the socio-demographics factors between the intervention and control groups.

<insert Table 1 here>

Follow up data was available for 34 service users, with a total retention rate of 71%, comprising 85% in the intervention group and 52% in the control group (see CONSORT diagram, Figure 1).

<insert Figure 1 here >

Clinical effectiveness outcomes

Quantitative data

We found no within group differences in scores (9-months follow up vs baseline) on the primary outcome (EQ-5D-5L) or any of the secondary clinical outcomes (ReQoL-10; MMTBQ De Jong Gierveld (total); Emotional loneliness score; Social loneliness score) between the intervention and control groups (Tables 2 and 3).

<insert Table 2 and Table 3 here>

Implementation outcomes

Acceptability of Intervention Measure (AIM)

Six service users and six Health Champions completed this measure. Both service users and Health Champions had a median score of 17.5 (range 15-20). The IQR for both was 4.

Secondary outcomes-Feasibility of Implementation Measure (FIM)/ Intervention Appropriateness Measure (IAM)

Four service users and three Health Champions completed the FIM with a median score of 16 (range 15-20). Six service users and six Health Champions completed the IAM with a median score of 16 (range 16-20).

Adoption and sustainability

Twenty-seven service users were randomised to the intervention group. Three were not matched with a Health Champion as they withdrew from the study. Of the 24 matched, three had an introduction session only, while 21 had at least three sessions. Fourteen (58%) of the matched service users completed at least 8 months of the intervention; the mean number of months completed was seven. Reasons for people finishing early included changes in service user or Health Champion circumstances or service users feeling that they no longer required the support. The number of sessions received ranged from 3 to 32 with a mean of 20 sessions per participant.

Qualitative interviews

Of all service users and Health Champions 16 services users and 16 Health Champions agreed to be interviewed.

We asked service users about the benefits they had experienced from having a Health Champion. 14 participants reported that they had made some changes to their physical health. This included four participants reporting losing weight, and two stating that they were no longer pre-diabetic. Five service users said that they were doing more exercise, and five had made changes to their diet. One participant had cut down on their tobacco smoking. Two reported that they had developed a more positive attitude to exercise and nutrition. Furthermore, six participants reported that they had made changes to other areas of their life including being more confident and less anxious.

The main themes from service user and Health Champions experience of the intervention with illustrative quotes are shown in Table 4. The themes identified are summarised below.

Service users and Health Champions generally found the intervention acceptable which echoes the findings from the implementation outcome measures. They mostly considered it feasible and appropriate to undertake. In terms of fidelity, service users and Health Champions considered having a focus on physical health alone, which did not consider mental health and other aspects of their life, unhelpful in thinking

about making changes as they did not experience these aspects of their life as separate from each other.

Implementation barriers identified by both service users and Health Champions included the social distancing required due to the COVID-19 pandemic and issues with arranging to meet due to other considerations such as starting college or long work hours for some Health Champions. For service users, one specific identified barrier was that even with support from a Health Champion they still found motivation difficult, whilst for a minority of Health Champions a barrier was a perceived lack of clarity about their role as this made them unsure of their role.

The main implementation facilitator for service users was the relationship built with the Health Champion, with trust commonly cited as a key factor enabling them to be open about their experiences which helped them to make changes to their physical health. For Health Champions two main implementation facilitators were the reward they enjoyed from the role, and the support they received both in supervision sessions and from the project team. This support helped them to feel secure in the role.

No unintended consequences were reported from service users taking part in the intervention or Health Champions delivering it. Service users also reported on their experience of the intervention, in particular noting that having a Health Champion was seen as a powerful factor that allowed them to make changes to their life such as making changes to their physical health.

<insert Table 4 here>

Cost analysis

Over the period of trial, intervention costs amounted to an estimated total of £8,422: £312 per participant and £337 per Health Champion in the intervention arm of the trial. Practitioner time allocated to supervision and support of Health Champion volunteers accounted for the highest proportion of total implementation cost (51%) (table 5). Further details of costs can be found in Appendix 4.

<Insert Table 5 here>

27 randomised service users completed a health service use questionnaire at 9-months post randomisation (response rate 56%). For the sub-sample with complete data, costs arising from wider reported contact with health services were mainly associated with primary care usage, along with outpatient and emergency department visits (table 6). Unadjusted mean total costs (Table 6) were lower for the intervention group than the control group with complete data (-£606; 95% CI -£1,170 to -£42). This difference did not persist after adjusting for baseline covariates (£-345; 95% CI -£909 to £219).

<Insert Table 6 here>

Discussion

We found that the majority of service users who took part in the Health Champions intervention viewed the experience as acceptable, feasible and appropriate. 63% of service users reported that they had made changes to their physical health, including losing weight and being more physically active. Some reported making other changes such as increasing their confidence. The volunteers also overwhelmingly experienced their involvement as positive.

As this was a feasibility study it was not powered to detect any differences in the size of the effect between our intervention and control groups, but we were interested in understanding the impact of the intervention. Our analysis was an ITT analysis and we also conducted an analysis with those participants who had a complete base line and follow up data and we did not observe any changes with the total scores (see appendix 5).

We did not conduct a full economic evaluation. We found some changes in wider healthcare utilisation with lower costs for the intervention participants. The lower cost of health care contacts could indicate that support from Health Champions changed health care use however there needs to be caution in interpreting any economic findings due to the small sample size, but this is something that could be investigated further in a larger trial.

The perceived benefits reported by the service users are consistent with previous studies exploring volunteer support of people with SMI which identified that the relationship built between volunteer and service user was paramount (28, 29). In our study, service users reported the relationship with their Health Champion as key to making the desired changes to their physical health. Having someone involved who was seen as ‘independent’ of health services was important for some service users and this has also been reported in other studies (30). The main reported barriers for the Health Champions were practical issues such as their availability changing so they could not give the time they wished to the role. This reflects findings from other studies that this type of volunteering is a significant commitment for volunteers (31). We have learned that volunteers appreciate having both group and individual support and a named contact when supporting people with SMI in the community. Making sure volunteers are effectively supported is key to any intervention involving volunteers (16) and this support needs to be factored in when costing n intervention such as this (32).

A main strength of this study was that Implementation Science methodologies were used to rigorously evaluate the feasibility of implementing a novel intervention including evaluating clinical, implementation and cost effectiveness in one hybrid trial. There were two main limitations of the study due to conducting the trial during restrictions due to the COVID-19 pandemic. Firstly, we were not able to recruit the number of service users anticipated as the recruitment processes that we had planned were interrupted, namely visiting recruitment sites in person and spending

time in the sites to make staff and service users aware of the study. Research has shown that this contact facilitates recruitment (33). This barrier may have been temporary and may not be a hindrance in a future evaluation of this intervention. Secondly, the trial was delayed due to the pandemic, so we were no longer able to undertake assessments six months after the intervention finished as originally planned. This meant that we had two assessment periods only (baseline and at end of intervention) instead of the planned three.

This Health Champions intervention has been found to be a feasible and acceptable intervention to support people with SMI with their physical health, with qualitative evidence of perceived benefit. Any organisation that wishes to use this model needs to plan the implementation and evaluation of this approach carefully. Three main aspects need to be considered.

Firstly, in terms of cost, the intervention is relatively low cost but adequate implementation support for the Health Champions is needed for the intervention to be feasible. This support includes regular supervisory contact with Health Champions to allow them to share and discuss any issues arising, and support if the person they are matched with has any crises.

Secondly, care needs to be taken in identifying which clinical outcomes are most appropriate and meaningful, and how they should be measured. We found that identifying the best outcome measures to assess clinical effectiveness was challenging. This was not a trial of one physical health condition so we could not use diagnosis-specific outcomes. Although the trial design was not powered to detect a quantitative difference, it is also possible that the five domains of QOL measured in the EQ-5D-5L questionnaire were not impacted by the intervention. For example, unless a participant had problems with mobility then having a Health Champion was unlikely to make any changes to this. Two possible solutions should be considered in a larger trial. First, any assessment of change of each service user's stated goal could be done using an individual. There are methodologies that have been developed to do this including PSYCHLOPS (25) where service users identify and score the areas that are problematic for them, and the difference in their score of these problems before and after an intervention is calculated. This has the benefit of ensuring that any change is related directly to a person's individual daily life. Second, consulting advisory groups that include people with lived experience and volunteers in discussions on what outcomes should be measured would help ensure the outcomes chosen were meaningful (15).

Thirdly, from an implementation perspective, we selected a number of questionnaire scales (i.e. AIM, IAM and FIM) that have been previously evaluated psychometrically and are also brief, so expected to be easier to administer (25). However, we found that the uptake of the scales was very poor. From our experience in the trial we suggest that this was sometimes due to participant fatigue, as they were administered after completing an interview and the other outcome measures.

Further, some service users and Health Champions found the wording of the questionnaires difficult as they did not correspond to their experience of having or being a Health Champion. Consulting potential participants in selecting and potentially editing suitable implementation assessment instruments in the context of a larger study is recommended.

A future definitive trial would be beneficial to understand the mechanisms involved in helping participants to make the behaviour changes necessary to improve physical outcomes as well as quantifying clinical and cost-effectiveness.

Declaration of Interest statement

NS is the director of the London Safety and Training Solutions Ltd, which offers training and improvement and implementation solutions to healthcare organisations and the pharmaceutical industry. FG has received support or honoraria from Boehringer Ingelheim, Lundbeck, Otsuka and Sunovion. The other authors have no conflicts of interest to declare.

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Authors contribution statement

The study was conceived by IM. The study was designed by JW, EF, RM, UA, IM, EG, FG, ES, ZK and NS with input from AH on economic evaluation and IB on statistical analysis. IB and JAT provided statistical analysis and AH economic evaluation. JW, RM, MP and ES undertook the qualitative analysis. JW drafted the manuscript with input from all other authors. All authors approved the submitted version of the manuscript.

Transparency declaration

I affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data availability

The data that support the findings of this study are available from the corresponding author, JW, upon reasonable request.

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Table 1 Baseline characteristics of the service users by group and total

			Intervention (n:27, 56.25%)		**Control (n:21; 43.75%)**	
	n	**%**	**n**	**%**	**n**	**%**
Gender						
Female	27	56.25	18	47.62	10	58.33
Male	21	43.75	9	52.38	11	41.67
Ethnicity						
Black	22	45.83	10	37.04	12	57.14
White	18	37.50	12	44.44	6	28.57
Mixed/other	7	14.58	4	14.81	3	14.29
Did not want to say	1	2.08	1	3.70	-	-
Education level						
No qualification	3	6.25	2	7.41	1	4.76
GCSE or equivalent	13	27.08	8	29.63	5	23.81
A level or equivalent	16	33.33	8	29.63	8	38.10
Degree or equivalent	15	31.25	8	29.63	7	33.33
Other qualification	1	2.08	1	3.70	-	-
Living arrangements						
Alone	26	54.17	13	48.15	13	61.90
Spouse or partner	4	8.33	2	7.41	2	9.52

Spouse and children	3	6.25	2	7.41	1	4.76
With children	6	12.50	5	18.52	1	4.76
Other relative	4	8.33	1	3.70	3	14.29
Other not related	2	4.17	2	7.41	-	-
Supported accommodation	3	6.25	2	7.41	1	4.76
Employment status						
Employed	8	16.67	4	19.05	4	16.67
Unemployed	33	68.75	21	57.14	12	68.75
Education	7	14.58	2	23.81	5	14.58
Relationship status						
Single	37	77.08	20	74.07	17	80.95
In a relationship	4	8.33	2	7.41	2	9.52
Married	5	10.42	3	11.11	2	9.52
Divorced	2	4.17	2	7.41	-	-
Median age (IQR)	39	18.5	41	18	37	13

n: number of individuals; %: percentage; IQR: interquartile range;

Table 2 Total scores in the primary and secondary outcome measures overall and by study group

		All service users			Intervention group			Control group		
		n	**Median**	**IQR**	**n**	**Median**	**IQR**	**n**	**Median**	**IQR**
Baseline										
EQ-5D-5L		47	0.80	0.36	27	0.76	0.38	20	0.80	0.38
ReQoL-10		48	21.5	12	27	20	11	21	23	15
MMTBQ		48	20	26.25	27	20	35	21	27.5	17.5
De Jong Gierveld (total)		47	4	2	26	4	2	21	4	2
Emotional loneliness score		48	2	2	27	2	1	21	2	2
Social loneliness score		47	3	2	26	3	2	21	2	3
Follow up										
EQ-5D-5L		34	0.78	0.34	23	0.76	0.41	11	0.85	0.39
ReQoL-10		33	24	12	22	23	14	11	28	15
MMTBQ		33	20	22.5	22	25	22.5	11	20	22.5
De Jong Gierveld (total)		33	5	3	22	5	3	11	4	3
Emotional loneliness score		33	2	1	22	2	2	11	2	1
Social loneliness score		33	3	1	22	3	1	11	3	2

n: number of individuals; IQR: Interquartile range; ReQoL-10: Recovering Quality of Life – 10; MMBTQ: Multimorbidity Burden Treatment Questionnaire.

Table 3 Difference between baseline and follow-up primary and secondary clinical outcome scores within the study groups (intra-group) at baseline and follow up.

	Intervention group			Control group		
	n	**MD**	**95% CI**	**n**	**MD**	**95% CI**
EQ-5D-5L	46	-0.01	-0.19-0.18	22	0.10	-0.15-0.36
ReQoL-10	45	1.68	-3.39-6.75	22	2.27	-5.05-9.60
MMTBQ	46	0.00	-0.44-0.44	22	0	-0.39-0.39

De Jong Gierveld (total)	44	-0.36	-0.54-1.27	22	0.27	-130-1.85
Emotional loneliness score	44	0.45	-0.13-1.04	22	0.36	-0.75-1.47
Social loneliness score	45	-0.09	-0.68-0.50	22	-0.09	-1.12-0.94

n: number of participants; MD: mean difference; 95% CI: 95% Confidence Interval;. Model 1: adjusted for baseline score in the questionnaire; model 2: adjusted for baseline score in the questionnaire and gender, Ethnicity, education level, living arrangements, employment status, relationship status and age.

Table 4: Qualitative evaluation of Implementation Outcomes

Implementation outcome	**Themes and quotes**	
	Service users	**Health Champions**
Acceptability	Overall service users found the intervention acceptable. Participants found Health Champions helpful in providing support and encouragement. '*It's helpful to have the support, someone there to talk to. Yeah, it's good to have someone there to talk to and help meet targets and goals*.' ID2 '*they give good advice, they give practical things that you can do. The one I had was very cheerful, makes you feel good'* ID10	Health Champions generally found the experience acceptable and enjoyable. *'It was fun. It was nice talking to him.'* ID11 *'Overall, I found it very easy and not taxing at all or difficult to navigate.'* HC10
Feasibility	Most service users were happy with how often they met with their Health Champion and reported that they found taking part easy and that there was good communication with their Health Champion. '*I really enjoyed it because I though the pair that I was given, the Health Champion I was given was a really good match*.' ID45 '*we'd just talk on the phone and arrange to meet up like that.*' ID39 '*I was able to talk about my physical health and what I need to do, what steps I need to take.*' ID42	Most Health Champions found it was Feasible to be a Health Champion. For some, if their circumstances changed it became more difficult to continue giving the time needed. *'I was lucky that I work quite near where she was, so I could go there quite easily.'* ID1 *'Only lately it's become more complicated because I've started a new job.'* HC4

Appropriateness	Most service users felt that the support from their Health Champions was appropriate for them, it was relevant and suited their needs. '*It's not a push thing. So, that's what's made it easier for me. That's probably why I lost the weight and probably why I feel like I could carry it on. It didn't feel like no burden or no pressure on me'* ID22	Most Health Champions found the role Appropriate for them and their life. '*I volunteered cos I knew by doing this it's gonna empower me to get back out and to be able to connect. And it 100% has done that*.' HC6 *'So, that was alright, even though it is a difficult thing, but it never felt verwhelming*.' HC10
Fidelity	The focus of the intervention was on Physical health but most service users also discussed other aspects of life as people felt it was not helpful to separate physical health from other aspects of life as they were so inter-related. '*I have memory loss from the medication, and then she helped me to find a memory game so I can play on something like that*.' ID42 We talked about '*loads of things: a boyfriend, family, childhood. Lots of conversations*.' ID35	Health Champions also said that separating physical health from other aspects of people's life was often not helpful. *'If you wanted him to look at his physical health…you had to take into account how much he could do and how much to support him…This way he was supporting his mental health and his physical health.'* ID3 *'She did talk about her physical health sometimes, But It was usually a much broader conversation.'* ID16
Barriers	Three barriers were identified. One was meeting with their Health Champion if both were busy or if it was done by phone. *'it was hard to meet up when I started working extremely hard and my health champion also was working very hard'* ID45 '*once a week talking to someone Over the phone for one hour, you don't get to bond with that person'* ID11 The second was the service users being motivated to make the changes they wanted to make even with the support of the Health Champion.	The barriers identified included defining the role: '*the role was so broad, maybe I tried to do too much or the wrong thing*.' HC1 Communication '*The biggest challenge was scheduling the calls and actually getting to have the phone calls*.' HC13 Finding time '*I think the timing wise was just wrong: me trying to do it during the most stressful academic year*.' HC2

	'*I think it's motivation to actually do The things that I know are good for me…I don't know how to explain it, but I just can't do some things*.' ID35 The third barrier was the impact of COVID-19. '*if it wouldn't have been for the Covid times, it would've been a lot better. I think it would've been a lot more easier to meet up*.' ID11	
Facilitators	The main facilitator identified was The relationship built with the Health Champion-this relationship helped service users to feel listened to and so be able to confide in the Health Champion. '*She's an amazing person. I really appreciate her time and her empathy'* ID45 ''*it's a good match and I also think it's because she was also very knowledgeable when it came to diet and physical exercise. But I also think she was very understanding*.' ID41	Facilitators for Health Champions were: The reward they found doing the role '*I personally found that really interesting and really rewarding,*' HC7 The supervision sessions *'It was good because it was a chance for me to hear from other health champions and see how they getting on.*' HC17 '*I like the way the supervision was because he was saying, 'If you can make it, it's here for you'*.' HC6 The support from the volunteer coordinator and research team '*I knew that, when I did start to think, 'This Is getting a bit too much,' I felt like I could approach everyone'* HC2 *'There was always the opportunity to contact somebody if you needed to…You didn't feel alone at all.'* HC8
Unintended consequences	No unintended consequences were reported. When asked this question service users reported on life events and the impacts these had had on their experience of the intervention.	

Experience of The intervention	When asked about their experience of the intervention service users talked about how taking part in the intervention had helped them *'it made me feel as though I'd achieved something. So, it helped with my mood. So, it was a goal that I could achieve'* ID13 *'I'm happy because I've made a lot of changes to my lifestyle'* ID35 *'Before I was having help from [NAME]…I was just in such a dark place and I didn't think I was ever gonna get out of it and get better. But, since the help that I've had, I've been doing a lot every single day*.' ID41 *'It has made me feel more positive about my physical health and about my self-image*.' ID45	Health Champions talked about what they had got from taking part '*challenging, rewarding and astonishing'* ID3 '*It was a good experience because I learnt a lot*.' ID5 '*The person I was paired with, she was just fantastic'* ID17

Table 5: Costs of the Health Champions intervention

	Cost	**% contribution to total intervention costs**
Supervision and support of volunteers to be Health Champions	£4,279	51%
Training	£2,355	28%
Recruitment of Health Champions	£761	9%
Equipment expenditure	£635	8%
Matching	£392	5%
Total	**£8,422**	NA
Cost per Health Champion	**£337**	NA
Cost per trial participant	**£312**	NA

%: percentage; £: pounds sterling; NA: not applicable

Table 6: Health care utilisation and total costs over 9-month Health Champions intervention period[1]

	Control group		
	Mean reported contacts (SD)	**Mean cost (SD)**	N
GP contacts	7.00 (7.96)	£280 (£319)	11
Outpatient visits	3.36 (2.87)	£673 (£575)	11
A&E contacts	0.82 (2.40)	£243 (£713)	11
Acute care bed days	0.09 (0.30)	£86 (£286)	11
Psychiatric bed days	0.00 (0.00)	£0 (£0)	11
Total cost (mean, SD)	**£1,283 (£861)**		**11**
	Intervention group		
	Mean reported contacts/beds days (SD)	**Mean cost (SD)**	N
GP contacts	4.47 (7.05)	£179 (£283)	17
Outpatient visits	2.06 (2.57)	£413 (£514)	16
A&E contacts	0.50 (1.03)	£149 (£307)	16
Acute care bed days	0.00 (0.00)	£0 (£0)	16
Psychiatric bed days	0.00 (0.00)	£0 (£0)	16
Total cost (mean, SD)	**£938 (£567)**		**16**
	Difference in group mean (N=27)	**95% CI**	
Mean overall cost of wider health care utilisation: unadjusted	-£606	-£1,170 to -£42	
Mean overall cost of wider health care utilisation: adjusted	-£345	-£909 to £219	

1. Health use reported for a 6-month period prior to interview at 9-month after beginning of intervention. SD = standard deviation; CI = confidence interval; £: pounds sterling

Figure 1 CONSORT diagram