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The SPACES feasibility trial: a co-produced physical activity intervention for people with severe mental illness

Abstract

Background: People with severe mental illness (SMI) experience a lower life expectancy compared to the general population. Taking part in regular physical activity can decrease the risk of physical health conditions (e.g. cardiovascular disease). People with SMI are less physically active than those without SMI. This is due to a variety of factors. Currently, physical activity interventions are not a part of standard care for people with SMI. Interventions that have been examined have lacked lived-experience input and produced limited engagement. An intervention has been co-produced to support people with SMI to increase their levels of physical activity.

Methods: The feasibility of delivering the *Supporting Physical Activity through Coproduction in People with Severe Mental Illness* (SPACES) intervention was evaluated in a two-armed randomised feasibility study. The recruitment and follow up processes, and the acceptability and suitability of the intervention were assessed. Physical activity levels were measured using an accelerometer. Progression to a definitive study was evaluated in accordance with set a priori criteria.

Results: In total 73 people consented and 71 people were randomised across 6 National Health Service (NHS) sites. Thirty-five were allocated to the control and 36 to the intervention. Nine people formally withdrew from the study; 8 from the control and 1 from the intervention. Overall follow-up rates of 87% and 76% were observed at the 3- and 6-month follow-ups respectively. The group intervention was delivered by NHS staff at all six sites.

Conclusion: The SPACES feasibility study met the pre-determined progression criteria to a definitive randomised controlled trial.

Introduction

People living with severe mental illness (SMI) experience a mortality gap of 15-20 years compared to the general population[1,2], with over 70% of deaths attributed to preventable physical health conditions[3]. Addressing the health inequalities experienced by people with SMI is a priority in the United Kingdom National Health Service (NHS) Long Term Plan[4]. Failure to meet physical activity (PA) guidelines is one of the leading causes of avoidable mortality and morbidity in the United Kingdom (UK)[5]. Research has demonstrated that people with SMI typically engage in excessive amounts of sedentary behaviour and low levels of physical activity[6,7]. Furthermore, people with SMI experience multiple unique barriers to taking part in physical activity such as mental health symptoms, side effects of medication, finance, feelings of vulnerability and social anxiety, and lack of social support[8,9,10].

In the wider population, there is robust evidence that higher levels of PA can reduce the risk of cardiovascular disease, diabetes and metabolic syndrome[5] which are all substantial and disproportionate problems in people with SMI[2]. A systematic review, however, has identified that current interventions seeking to increase PA have been poorly designed, had limited lived experience input, lacked power and have ultimately not been successful in engaging people with SMI [7]. There is also limited evidence for the effectiveness of particular approaches and components within interventions tested to date due to small sample sizes and poor reporting, restricting the ability to draw firm conclusions[11]. As a consequence, interventions to promote PA are not routinely offered to people with SMI in clinical settings such as the NHS. To overcome this gap, authors[10] have argued the importance of taking an individualised approach (i.e. one that acknowledges values, self-identify, personal and social circumstances, and cost of the activity) to PA promotion in people with SMI, whilst also recognising the wider determinants and complex dynamic drivers of PA behaviour in this population[12]. With this in mind, the SPACES programme (Supporting Physical Activity through Co-production in People with Severe Mental Illness) was funded to co-produce and evaluate the feasibility, effectiveness and cost-effectiveness of a PA programme for people with SMI. The development of the SPACES intervention has been reported elsewhere[13]. In this article we report on the SPACES randomised controlled feasibility trial that was done to inform a subsequent definitive trial[14].

The aims of the SPACES feasibility trial were:

- To quantify the flow of participants and evaluate proposed recruitment, assessment, outcome measures, and data collection methods within the SPACES feasibility trial.
- To examine the feasibility of delivery of the SPACES intervention
- To assess the acceptability of the intervention
- To refine the SPACES intervention in light of any identified areas for improvement following initial implementation
- To use accelerometer-derived minutes per day of moderate-to-vigorous intensity physical activity (MVPA) to inform the sample size calculation for a phase-III, randomized controlled trial (RCT).

Methods

Study Design and participants

The SPACES feasibility trial was a pragmatic, two-arm, parallel group, randomised controlled trial (RCT). The protocol for the trial has been reported elsewhere[14]. The trial was registered prospectively with the ISRCTN registry (ISRCTN83877229. Registered on 09.09.2022) and results are reported in accordance with CONSORT guidance for pilot and feasibility studies[15].

Data from this study, including reported rates of consent, recruitment and follow-up, and outcome measures, summarised overall and by randomised group, were used to inform sample size estimation and feasibility for a full-scale RCT.

Participants were recruited across six geographically dispersed NHS mental health trusts in England. Participant eligibility criteria were:

- Age: 18 years or over
- A primary International Classification of Diseases (ICD)-10 or Diagnostic and Statistical Manual of Mental Disorders (DSM)-V diagnosis of SMI (schizophrenia, delusional/psychotic illness or bipolar disorder) as documented in General Practitioner (GP) or psychiatric notes
- Able to walk unaided
- Willing to wear an accelerometer at baseline

Exclusion criteria were:

- People who lacked capacity to participate in the trial as guided by the Mental Capacity Act (2005)[16]
- Primary diagnosis of drug or alcohol abuse
- A medical contraindication to physical activity as ascertained by GP or mental health team
- Already physically active (defined as >300 min/week of self-reported MVPA)
- Unable to communicate in English.

All participants provided written informed consent to take part in the study. Ethical and Health Research Authority approval was granted on the 18th August 2022 by the West of Scotland Research Ethics Committee 5 (22/WS/0101).

Procedures

Potential participants were identified by NHS clinicians or via research databases. Eligibility, based on diagnosis by a psychiatrist, was confirmed by researchers who would then contact appropriate service users. Those who expressed an interest in taking part were invited to discuss involvement in the trial with a local NHS site researcher. Following this discussion, if the person met the eligibility criteria and remained interested in participating in the study, written informed consent was taken. Eligible and consenting participants completed a baseline questionnaire with support from a trained NHS researcher. In addition, participants were asked to wear an accelerometer for 10 days to collect data on

PA and sedentary behaviour. The NHS researcher then met with the participant to collect the accelerometer and randomise the participant via *SCRAM*. Participants were followed up at 3 and 6-months post randomisation, to complete follow-up questionnaires, a weight measurement, and were asked to repeat the 10-day accelerometer wear time. Participants who completed follow-up assessments were thanked with a £20 voucher for each completed follow-up.

All trial participants continued to receive their usual NHS care and were provided with the UK Government leaflet which outlined UK PA guidelines[17]. Participants who were allocated to the intervention were also offered the SPACES intervention.

Randomisation and masking

Allocation was through block, 1:1 randomisation (with random permuted blocks of sizes two and four) with a separate schedule for each site. The study statistician at Sheffield Clinical Trials Research Unit generated the randomisation schedule prior to the start of the study using their web-based in-house *SCRAM* randomisation system. Allocation concealment was ensured as the secure web-based system did not release the randomisation code until the participant had been recruited into the trial (post baseline measurements completed). Details of the block size were not communicated to the study team.

Due to the nature of the intervention blinding of the participants, clinicians and the researchers was not possible. However, those involved in trial data analysis were blind to group allocation until the statistical analysis plan was signed off.

SPACES intervention

The SPACES intervention is a 20-week programme designed to help individuals with SMI initiate and sustain PA. The intervention was developed through an iterative process of focus groups and interviews with various stakeholders and a consensus group made up of people with severe mental illness, their carers, and professionals involved in physical activity and/or severe mental ill health. Full details of the intervention development process are detailed elsewhere[13]. Briefly, the intervention combines weekly group-based sessions with personalised one-to-one consultations, both of which are facilitated by trained Physical Activity Coordinators (PACs). PACs receive structured training, a delivery manual, and ongoing support to ensure consistency in intervention delivery. Participants engage in up to 18 group sessions, each comprising 60 minutes of graded PA (e.g., walking, indoor classes, community tasters), 30 minutes of themed discussion on topics like motivation and overcoming barriers, and 30 minutes of informal social time. One-to-one consultations (up to 5 per participant) are delivered at key points: entry, mid-point, and exit, and are tailored to individual needs, goals, and preferences, including options for face-to-face, phone, or video formats. The total number of one-to-ones delivered is determined by participant choice/need. Additional support includes self-monitoring tools, a participant handbook, session reminders, and peer/professional social support. The intervention is grounded in behavioural-change theory, co-production, and behaviour change techniques, with flexibility built in to accommodate individual exertion levels.

Feasibility measures

It was pre-specified that in order for a full-scale SPACES RCT to be feasible the feasibility study needed to recruit at a rate of 2 participants per site per month and we aimed to recruit between 48 and 72 participants from 4-6 centres over 6 months. This is in line with recommended sample sizes for pilot and feasibility studies[18,19,20,21].

Outcome measures

The main objectives of this feasibility study were to explore the i. feasibility and acceptability of the PA intervention and trial evaluation procedures, ii. the central parameters for the design of a full-scale trial were explored. This included estimates of the variability around the proposed primary outcome for the full scale RCT (accelerometer-derived MVPA), and an estimate of the intracluster correlation coefficient The acceptability of the proposed secondary outcome measures for the full scale RCT were also explored, these included PA and sedentary behaviours (accelerometer-assessed metrics including MVPA, and Simple Physical Activity Questionnaire [SIMPAQ]19, body mass index [body mass (kg) /stature (m)], depression [PHQ-920], anxiety [GAD-721], health-related quality of life [EQ5D22], SF-1223, REQoL24, and healthcare resource use collected via a bespoke questionnaire designed for SPACES. Participants completed outcome measures at baseline, 3 and 6 months post randomisation.

The acceptability of the intervention was explored using the acceptability of intervention measure (AIM) [15] which all participants in the intervention arm were invited to complete at 6-month follow-up. No pre-specified thresholds were determined for the AIM. Qualitative interviews were conducted with 15 people who received the intervention and five PACs. The results of the qualitative interviews have been reported elsewhere[22]. Data was also collected on intervention uptake, attendance, and attrition.

The feasibility of the trial procedures was evaluated through recording the number of potential participants who; were screened, were eligible, agreed to participate, withdrew from the study. This information would inform whether any amendments to participant identification, recruitment, and retention approaches were necessary. Acceptability of the accelerometers (proposed primary outcome data collection tool) was assessed through monitoring accelerometer uptake and minimum acceptable wear-time achieved (16-hours per day for fours days, midnight to midnight with 3 weekdays + 1 weekend day).

Adverse events (AEs); any untoward medical events including unfavourable clinical signs or symptoms, development of a new disease or illness or exacerbation of a new disease or illness, were recorded from point of randomisation to 6-month follow-up. AEs that was life threatening, required inpatient hospitalisation or extension of existing hospitalisation, resulted in significant disability or incapacity, or resulted in death was recorded as a serious AE.

Statistical analysis

As the trial is a pragmatic feasibility study, the analysis was mainly descriptive and focused on confidence interval estimation with no formal hypothesis testing. Analyses were performed on the randomised population (intention to treat principle).

Accelerometer parameters were decided a priori. These included a daily minimum wear time of 16 hours (midnight to midnight), for at least 3 weekdays and 1 weekend day to be considered valid wear time, intensity cut off points of < 30 mg, 30-100 mg, 101-400 mg and > 400 mg (inactive, light, moderate and vigorous activity respectively). Mean MVPA per day was calculated on 5-s epochs with a 1-min bout duration with inclusion criteria of >80%. All days (≥ 4 valid days), weekends (≥ 1 valid days) and weekdays (≥ 3 valid days) were calculated. ActiGraph GT9X link[23] and Axivity AX6[23] accelerometers were utilized and programmed to 100-Hz measurement frequency rates. Accelerometer data were processed using GGIR v2.4–0[23] in R [http:/cran.r-project.org]. Instances of device failure during data collection resulting in missing MVPA data were recorded as accelerometer error.
As part of the feasibility analysis, we include estimation of the effect size for accelerometer-determined MVPA 6-months post-randomisation as a probable primary outcome for a full-scale RCT. Confidence interval estimates are reported to check that the likely effect is within a clinically relevant range (i.e. 95% CI includes a difference of 6 min of MVPA per day). We proposed to use a partially clustered mixed effects model with MVPA at 6-months as the outcome, baseline minutes of MVPA, site and randomized group as fixed effects and SPACES intervention groups as random effects. However, the model was revised to exclude site as a fixed effect to address collinearity arising from overlap between sites and groups in the study.

Health economic analysis

The aims of the economic evaluation of the feasibility study were to estimate the costs of intervention and to assess the acceptability of the data collection methods. No formal economic evaluation was carried out.
The intervention costs consisted of training costs of physical activity coordinators (PACs) and delivery costs. Training costs included staff time costs of trainers and PACs, costs of hard copies of manual, costs of venues, refreshments, and transportation if applicable. Delivery costs included staff time costs of PACs along with the budget for venues. Both training and delivery activities were recorded by the research team as the study proceeded. Staff time costs were estimated by multiplying respective hourly costs of staff by the time they spent. The training costs were allocated evenly to all participants in the intervention arm. All costs were presented in pound sterling 2022/23 price.
The self-report Case Report Form (CRF) was administered at baseline, 3 months and 6 months follow-ups. The data collected via CRFs included usual care physical activities, participant's use of medications and healthcare services, and EQ-5D-5L[24]. The medications were broadly divided into five types: antipsychotics, antidepressants, anti-anxiety medicines, medicines for mania or hypo-mania, and medicines for other mental health considerations. The services broadly covered primary and community care services, secondary care services, and emergency care. Participants were allowed to add

medications or services if they were not on the provided lists. The EQ-5D-5L was used to measure health-related quality of life. A complete profile of the five domains was converted to a utility score, using the recommended mapping approach[25].
The completeness of questionnaires was used to assess feasibility of data collection. The results were analysed descriptively and used to identify infrequently used medications and services and those frequently used but not specified by the research team. They were then used to revise the contents of the CRF for the future full trial to strike a balance between the need for information and burden of answering.

Results

Participant recruitment and flow

Between December 2022 and April 2023, 71 participants were recruited and randomised (35 intervention: 36 usual care) to the SPACES feasibility trial (Figure 1); an average of 3 per site per month. This met our pre-specified target of 2 participants randomised per site per month with a consent rate of 73/162 i.e. 45%. Baseline characteristics of the sample are presented in Table 1.

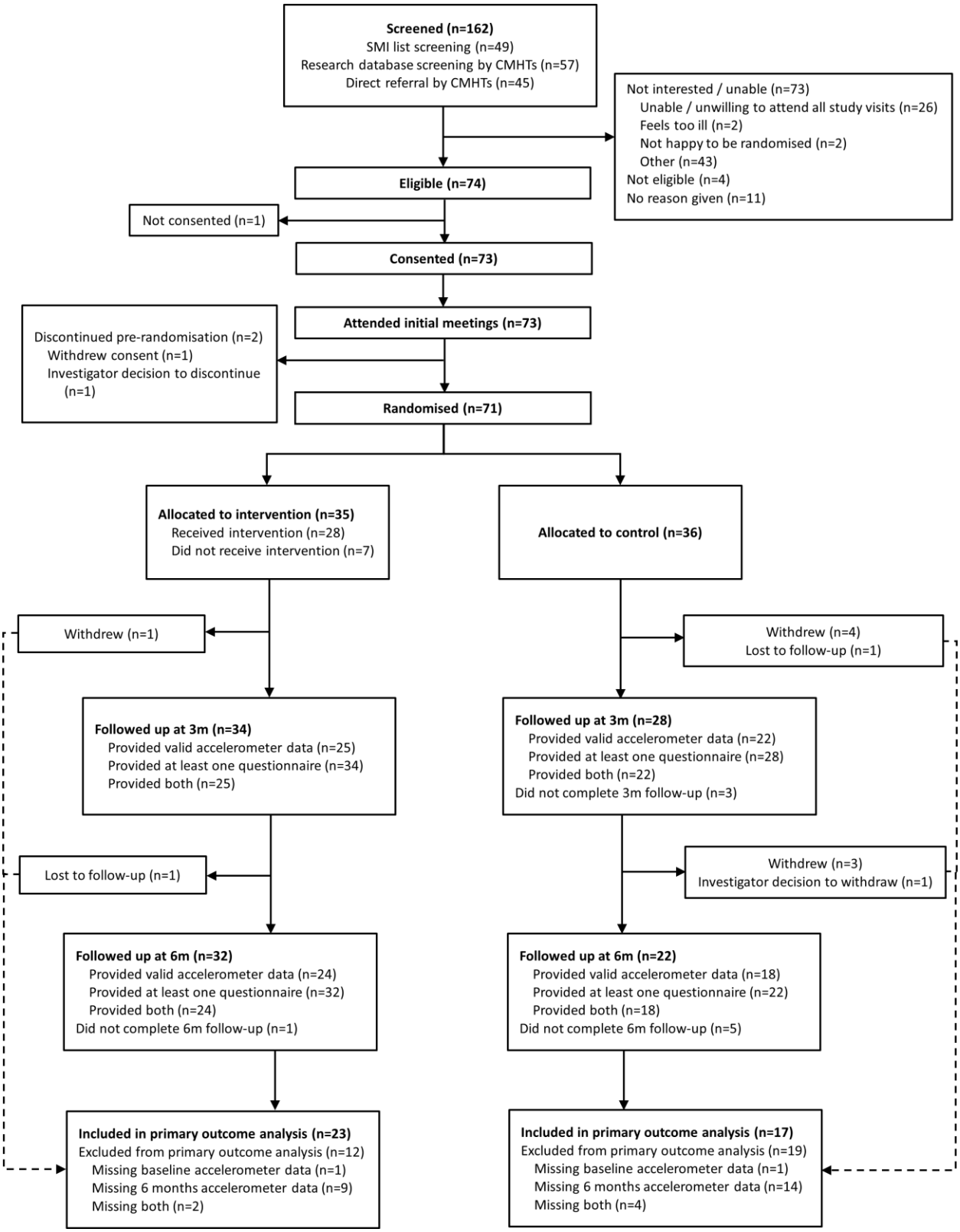

Figure 1: CONSORT flow diagram

Table 1: Baseline characteristics

	Usual care N (%) N=36	Intervention N (%) N=35	Overall N (%) N=71
Sex			
Male	19 (53%)	19 (54%)	38 (54%)
Female	17 (47%)	16 (46%)	33 (46%)
Ethnicity[23]			
White	27 (75.0%)	24 (68.6%)	51 (71.8%)
Asian or Asian British	3 (8.3%)	1 (2.9%)	4 (5.6%)
Black, Black British, Caribbean or African	5 (13.9%)	8 (22.9%)	13 (18.3%)
Mixed or multiple ethnic group	1 (2.8%)	2 (5.7%)	3 (4.2%)
Diagnosis			
Schizophrenia (F20 and subcodes)	16 (44.4%)	15 (42.9%)	31 (43.7%)
Schizoaffective disorder (F25 and subcodes)	9 (25.0%)	3 (8.6%)	12 (16.9%)
Other psychotic and delusional disorders (not of known organic origin) (F21-24 and F26-29 and subcodes)	2 (5.6%)	4 (11.4%)	6 (8.5%)
Bipolar disorder and manic episodes (F30 and F31 and subcodes)	9 (25.0%)	13 (37.1%)	22 (31.0%)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	41.2 (9.5)	41.6 (11.7)	41.4 (10.6)
BMI (kg/m^2)	N=35	N=35	N=70
	33.0 (5.9)	31.8 (5.1)	32.4 (5.5)
Accelerometer-derived MVPA (minutes per day)	N= 31	N =32	N=63
	34.5 (29.2)	34.4 (29.6)	34.5 (29.2)
Accelerometer-derived time spent sedentary (minutes per day)	N= 31 470.8 (140.8)	N=32 454.9 (208.1)	N= 63 462.7 (177.0)

Full details of the flow of participants through the trial are detailed in Figure 1. A total of 9 participants formally withdrew from the trial.

Overall follow-up rates for the total sample (having completed at least one outcome measure) of 87% and 76% were achieved at the 3- and 6-month follow-ups respectively. A greater proportion of participants allocated to the intervention arm were followed up at each time point compared to the control arm (Figure 1).

Valid accelerometer data was available for 63 participants (89%) at baseline, 47 (66%) at three months, and 42 (59%) at 6 months. Accelerometer data availability was higher in the intervention arm than the control arm, with 25 (71%) vs. 22 (61%) at three months, and 24 (69%) vs. 18 (50%) at six months.

Acceptability of the SPACES intervention

See Table 2 for details of the attendance at the SPACES intervention.

Table 2: Intervention attendance*

Variable	Scoring	Intervention (N = 35)

Number of participants who withdrew from intervention	n	6
Group sessions attended (out of a possible 18)	n	35
	Mean (SD)	9.5 (7.01)
	Median (IQR)	11.00 (2.00, 16.50)
	Min, Max	0, 18
Individual meetings attended (out of a possible 5)	n	35
	Mean (SD)	2.9 (1.99)
	Median (IQR)	4.00 (1.00, 5.00)
	Min, Max	0, 5

**this table includes all thirty-five participants randomised to the intervention. Those who withdrew early or did not attend any sessions are included in the summaries as having attended zero sessions.*

Results of the Acceptability of Intervention Measure are detailed in Table 3. The majority of participants who completed the measure (n=30) either agreed or completely agreed with all four acceptability statements.

Table 3: Acceptability of the intervention

Variable	**Scoring**	**Intervention**
Data available for AIM	n	30
The SPACES intervention meets my approval	Completely disagree	0 (0%)
	Disagree	1 (3%)
	Neither agree nor disagree	0 (0%)
	Agree	13 (43%)
	Completely agree	16 (53%)
The SPACES intervention is appealing to me	Completely disagree	0 (0%)
	Disagree	1 (3%)
	Neither agree nor disagree	2 (7%)
	Agree	14 (47%)
	Completely agree	13 (43%)
I like the SPACES intervention	Completely disagree	0 (0%)
	Disagree	1 (3%)
	Neither agree nor disagree	3 (10%)
	Agree	13 (43%)
	Completely agree	13 (43%)
I welcome the SPACES intervention	Completely disagree	0 (0%)
	Disagree	0 (0%)
	Neither agree nor disagree	1 (3%)
	Agree	14 (47%)
	Completely agree	15 (50%)
Overall score*	Mean (SD)	17.5 (2.42)
	Median (IQR)	17.00 (16.00, 20.00)
	Min, Max	10, 20

A total of 11 adverse events were reported across 10 participants (5 in each arm) see Table 4.

Table 4: Summary of adverse and serious adverse events (AEs and SAEs) experienced by treatment arm.

		Usual care (n=36)	Intervention (n=35)	Total (n=71)
Total number of AEs and/or SAEs		6	5	11
Type of AEs	Injuries sustained as a result of an accident incurred traveling to or from a physical activity session	0 (0%)	1 (3%)	1 (1%)
	Other - Pre-planned surgery which required hospitalisation	0 (0%)	1 (3%)	1 (1%)
	Other - Rash on wrist due to wearing Accelerometer	2 (5%)	1 (3%)	3 (4%)
	Substantial increase in existing pain which failed to resolve within 72 hours following a physical activity session	0 (0%)	1 (3%)	1 (1%)
Type of SAE	Inpatient admission - Deterioration in mental health	3 (8%)	0 (0%)	3 (4%)
	Inpatient admission – Gastroenteritis	1 (3%)	0 (0%)	1 (1%)
	Risk of Persistent or significant disability or incapacity - detached retina	0 (0%)	1 (3%)	1 (1%)

Two AEs related to the intervention were recorded and no SAEs related to the intervention were recorded. Both related or serious adverse events were followed up and resolved by the end of the trial period.

Accelerometer-derived outcomes

Table 5 details the accelerometer-assessed minutes of MVPA per day at 6 months. Based on all valid MVPA readings across both trial arms at 6 months (n=42), the observed standard deviation of minutes of MVPA per day at 6 months was 28.2 (95% CI: 23.1 to 36.2).

Table 5: Accelerometer-assessed minutes of MVPA per day (averaged over 10 days) at 6-months follow-up of participants who provided valid accelerometer data at both baseline and 6 months

	Usual care			Intervention			Unadjusted mean difference[+] (95% CI)	Adjusted mean difference (95% CI)*	ICC
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)			
Baseline	17	30.99 (32.61)	21.86 (12.32, 40.49)	23	32.32 (28.58)	19.73 (10.30, 53.01)			
6 months	17	39.57 (33.82)	33.45 (19.83, 42.67)	23	31.45 (23.85)	32.08 (10.24, 47.50)	-8.13 (-27.8 to 11.55)	-8.86 (-24.97 to 7.26)	<0.0001

Abbreviations: ICC - intraclass correlation coefficient; SD - standard deviation; CI - confidence interval; IQR – interquartile range. Participants were included in the estimation of mean differences if they had available data for both baseline and 6 months.

[+]obtained from a t-test.

**obtained from partially clustered mixed effects regression model, using baseline MVPA and randomised groups as fixed effects covariates, and the SPACES intervention group was a random effect in the intervention arm only to account for clustering of participants within intervention groups.*

Details for average minutes of sedentary behaviour per day in the intervention and usual care arms is presented in Table 6.

Table 6: Accelerometer-assessed minutes of sedentary activity per day (averaged over 10 days) at 6-months follow-up

	Usual care (N=36)			Intervention (N=35)			Unadjusted mean difference* (95% CI)
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)	
Baseline	31	470.79 (140.76)	456.57 (371.65, 584.00)	32	454.90 (208.13)	445.59 (284.64, 572.58)	
6 months	18	436.86 (193.57)	393.71 (316.89, 568.31)	24	431.64 (224.81)	382.19 (258.70, 620.86)	-5.22 (-136.09 to 125.66)

Abbreviations: SD - standard deviation; CI - confidence interval; IQR – interquartile range. Participants were included in the estimation of mean differences if they had valid data at baseline or 6 months.

[+]obtained from a t-test.

Completion of the other outcome measures was not assessed as an outcome and therefore is not reported.

Health economic analysis

In total, 27 PACs received the nine days of training, which was delivered in three locations. All but two were group sessions. All trainers were members of the central study team. The salary bands of PACs ranged from NHS band 3 to NHS band 6. Including the opportunity costs of time of both PACs and trainers, costs of refreshments and transportation, and PAC manuals, training costs came to £16,925 in total, equalling £484 per participant.

The intervention arm consisted of six groups of participants. The group size ranged from four to seven. Among six groups, four groups successfully conducted 18 group sessions, one conducted 13 group sessions and one conducted 12. The mean number of group sessions attended was 9.5 (SD 7.0) per participant. Using the weighted mean hourly cost of all participating PACs (£22.40), the total staff costs of group sessions delivered were £8,333, on average £1,389 (SD £257) per group. The venue costs were budgeted as £100 per site per week, the budget of venue use amounted to £9,700 in total, on average £1,616 (SD £285) per group. Taking into account the different group size and attendance, the mean costs of group sessions were estimated at £517 (SD £392) per participant. Using the maximum scheduled duration for one-to-one sessions, the estimated costs of these sessions were £52 (SD £36) per participant. Each participant was provided with a handbook at £59 each. Overall, the mean intervention costs per participant were estimated at £1,112 (SD £404) in the intervention arm.

The pedometers cost £12.99 each but the distribution of them was not monitored. It was therefore not included above.

The completeness of data collected through CRFs showed that most missing data were due to lost-to-follow-up and single item missing was rare. Fewer than one-third of participants in each arm were given information sheets/booklets on physical activities or directed to related websites for information at all timepoints. Even fewer were directly referred to or prescribed structured programme or directed to another physical wellbeing professional, though some participants were given both indirect information and direct referral. At all timepoints, fewer than five participants in each arm reported taking up any activities.

All participants reported being on medication for mental health. Nearly all participants that were followed up reported taking antipsychotics. About half of the participants followed up at each timepoint took antidepressants. Hardly any participants took anti-anxiety medications. The situations where the listed medications were not reported by any participants and where participants reported medications that were not on the list, were both present.

The most contacted professional in community was community mental health team and community psychiatric nurse. GP was the most frequently contacted staff in GP practice in both arms and at all timepoints, followed by practice nurse. There was a low level of use of secondary care, especially outpatient procedures and outpatient appointments at hospital. All other services were seldom used.

Among those who had complete data at all three timepoints (21 in usual care; 32 in intervention), the mean utility score in the usual care arm increased from 0.769 (SD 0.182) at baseline to 0.779 (SD 0.180) at 3 months then decreased to 0.716 (SD 0.230) at 6 months, while in the intervention arm, it dropped

from 0.820 (SD 0.172) at baseline to 0.775 (SD 0.204) at 3 months and continued dropping to 0.771 (SD 0.204) at 6 months.

Discussion

To the best of our knowledge, the SPACES intervention is the first co-produced intervention specifically targeting increased PA for people with SMI. The results of this pilot study suggest it is feasible to conduct a full-scale RCT to assess this intervention, and the feasibility data has informed the design of a larger, funded trial, powered to determine the efficacy and cost-effectiveness of this intervention.

Feasibility of trial procedures

Overall, the methods and measures employed across the SPACES feasibility trial were found to be feasible and acceptable. The criteria for progressing to a full-scale trial; recruitment of 2 participants per-site per-month and ability to engage participants in follow-up data collection, were met and it was agreed by the independent Trial Steering Committee and the funder that the study should progress.

We identified procedures that could be refined to optimise the collection of the primary outcome of a subsequent full-scale RCT (MVPA data). There were three predominant factors pertinent to missing MVPA data across each timepoint; insufficient wear time, loss to follow-up, and accelerometer error. The parameters for valid accelerometer data were at least 16 hours a day for a minimum of 4 days (3 weekdays and 1 weekend day). This may be considered a conservative threshold for valid data compared to other studies with the same population. Across 26 studies, the parameters for valid data were observed to be as low as 6 hours to define a valid day and a minimum of 2 valid days, with no apparent stipulation as to weekdays/ends[17]. In light of this evidence, it was decided to revise the parameters for valid accelerometer data to 16-hour minimum wear time per day across 3 days without the stipulation between weekday and weekend days in the full-cale RCT. This stands to better balance the volume and quality of data collected, while remaining aligned with the wider research into physical activity among this population.

Another consideration was the impact of differential rates of withdrawal and follow-up between the intervention and usual care arms and how this impacted on collection of MVPA data from participants in the usual care arm. We therefore needed to explore how to promote retention of participants in the usual care arm of the trial. To achieve this, the SPACES Public and Patient Involvement and Engagement (PPIE) group were consulted, inviting their opinions on possible solutions. Through discussion with the PPIE group a resource was developed to be distributed to participants in the usual care group which explains the purpose and value of a usual care arm in an RCT. The PPIE group further advised that additional contact between NHS researchers and participants may promote better engagement and suggested a SPACES postcard which reminds participants of their follow-up appointments and elicits contact with researchers. Implementing the PPIE's postcard would also align with suggested strategies to promote retention among research participants with SMI by employing contact methods beyond a phone call to facilitate contact with study staff[17]. The PPIE group advised that the postcard should be a physical postcard sent in the post as it would be a tangible resource participants had in their homes to remind them of the trial, and also ensure that participants who did not have, or do not use, email were

not excluded. It would also demonstrate to the participants that their contribution was valued as sending out a physical postcard requires more effort than sending bulk emails.

The final amendment to trial procedures involved allowing for a wider window for follow-up data collection to take place, with 4 weeks +/- due date, opposed to 2 weeks +/- due date employed across the feasibility study. This was to reduce the loss of MVPA data due to accelerometer error, as an extended opportunity for data collection would allow researchers to identify incidents of accelerometer error and provide a more generous window in which to make contact with participants and to request re-wear of the accelerometer if needed. Trial procedures that facilitate a second attempt at data collection within a longer follow-up window would also further address MVPA data loss to insufficient wear time. If participants do not meet the threshold upon an initial attempt, it was decided that in the full-scale trial participants would be requested to wear the accelerometer again.

Through the costing exercise of the intervention, we identified missing information that should have been recorded and the inconsistency of recording. Data collected via CRFs suggested that it was feasible and acceptable to collect the required data this way. However, the use of various services was not common and certain services were seldom used, suggesting a shorter and simpler version may not influence the results. The responses to the medication list also suggested a slightly different group of medications were actually prescribed. We used this information to revise information requests for intervention costing and questions on CRFs for the full trial to balance the demand for information and burden of answering.

Sample size re-estimation for the definitive study

This feasibility study provided important information about the likely variation in the proposed primary outcome data (MVPA) and allowed the sample size for the definitive study to be recalculated to ensure sufficient power, i.e. our ability to detect true treatment differences in the definitive study.

The initial sample size estimate for the definitive SPACES RCT was based on a target difference of 6 minutes of MVPA between the groups, with a corresponding standard deviation of 22, 90% power, a two-sided 5% significance level were used, and the sample size estimation allowed for up to 15% loss to follow-up. These input parameters led to a sample of 670. The feasibility trial indicated that the standard deviation around the MVPA outcomes may be as large as 28, and that loss to follow-up was likely to be higher than 15%. The feasibility study also indicated a correlation between baseline and 6-month follow-up data of the primary outcome (estimated to be 0.60 (95% CI: 0.35 to 0.77), and provided no evidence of clustering of outcomes within intervention groups (ICC < 0.0001). Therefore, the total sample size for the definitive RCT was revised to 736 participants (368 per arm), in line with the following parameters:

Assuming a target difference of 6 minutes of MVPA/day; a SD of 28, equivalent to a small, standardised effect size of 0.21, a baseline to 6-month post randomisation correlation of 0.60 in the primary outcome measure and 90% power and 5% two-sided significance, then 588 participants (294 per group) would be required. Assuming 20% participant attrition, we would need to recruit and randomise 736 participants (368 per arm).

Feasibility of the SPACES intervention

Of 30 participants who completed the AIM, the vast majority agreed or completely agreed with positive statements, indicating a favourable perception and experience of the SPACES intervention. Similarly, measures of central tendency for attendance rate were over 50% across both group sessions and one-to-one engagement formats. Together these indicated general acceptability of the SPACES intervention, though evidently, scope to improve engagement and retention remains. Full details of refinements made to the SPACES intervention ahead of a full-scale RCT will be reported elsewhere in an intervention development manuscript. In summary, it was decided that the suggested group size for the intervention should be increased from 6 to 9 people. This group size would increase the likelihood of there being a viable group size even if some participants withdrew from the intervention or were unable to attend for any reason. There were no related SAEs that indicated cause for concern about the safety of the intervention or study procedures related to it.

Strengths and limitations

Owing to the logistical requirements of organising the intervention groups, it was not possible for researchers to be blinded to allocation throughout the trial. Though this may be somewhat mitigated by the objective nature of PA measurement employed here, the absence of blinding as a potential source of bias must be considered. As this is a feasibility study, the purpose was not to determine whether the intervention was effective, and the study was therefore not powered to detect a difference between intervention and usual care arm. Between group analysis have therefore, not been reported regarding intervention effectiveness. In addition those who are not able to communicate in English were not included in this study, posing an arguable limitation to the recruitment of minority groups who may be at heightened risk of developing physical health conditions following the onset of psychosis[26].

Nevertheless, the SPACES feasibility study was able to recruit a diverse sample, having been conducted in diverse regions across England including sites in both urban and rural locations in the North and South of England. Furthermore, 28% of participants were from a non-white British population indicating that our attempts to ensure diversity in our recruitment was successful. This is encouraging in terms of the acceptability of the intervention across both different geographical regions and in different populations.

Conclusions

This feasibility study found that the SPACES intervention was acceptable to participants and intervention delivery staff. In addition, the methods and measures employed across the SPACES feasibility trial were found to be feasible and acceptable. The criteria for progressing to a full-scale trial were met and it was agreed by the independent Trial Steering Committee and the funder that the study should progress. Conducting the feasibility study had added benefit, in that methods to optimise PA data collection were identified; reduction in the parameters for valid accelerometer data from 4 days to 3, the ability to offer re-wear of accelerometers where valid data has not been collected and, methods to increase engagement with the usual care group. These will be employed in the full-scale RCT. Furthermore, the intervention has been refined based on the findings from this study.

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Data availability

The anonymised dataset may be made available on reasonable request. Requests for data should be sent to the Sheffield University Clinical Trials Unit.

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Appendix/Supplementary

Table X: Summaries of secondary outcomes by follow-up and treatment group.

		Usual care (N=36)		Intervention (N=35)		
		n	Mean (SD)	n	Mean (SD)	Mean difference (95% CI)
Baseline	BMI (kg/m²)	35	33.0 (5.9)	35	31.8 (5.10)	
	PHQ-9	35	10.91 (5.93)	34	7.41 (6.36)	
	GAD-7	35	7.91 (5.41)	35	6.74 (6.33)	
	SIMPAQ: Bed	35	10.37 (2.00)	35	10.40 (2.30)	
	SIMPAQ: Sedentary	35	12.27 (1.75)	35	12.04 (2.23)	
	SIMPAQ: Walking	36	0.68 (0.50)	35	0.53 (0.37)	
	SIMPAQ: Exercise	36	0.07 (0.14)	35	0.11 (0.18)	
	SIMPAQ: Other	36	0.59 (0.67)	35	0.92 (1.37)	
	EQ-5D-5L	35	0.73 (0.23)	35	0.81 (0.19)	
	SF-12 (PCS)	35	45.36 (12.31)	31	48.81 (8.46)	
	SF-12 (MCS)	35	37.59 (12.22)	31	41.05 (14.09)	
	ReQoL-10	35	22.46 (7.56)	35	26.60 (8.37)	
	ReQoL-20	35	45.00 (15.01)	35	51.43 (17.01)	
3 months	BMI (kg/m²)	28	33.2 (5.8)	34	32.0 (5.3)	-1.2 (-4.1 to 1.6)
	PHQ-9	28	9.43 (6.24)	34	7.15 (5.39)	-2.28 (-5.29 to 0.73)
	GAD-7	28	6.39 (5.77)	34	5.94 (5.28)	-0.45 (-3.29 to 2.39)
	SIMPAQ: Bed	28	9.25 (2.89)	34	10.21 (1.97)	0.96 (-0.34 to 2.25)
	SIMPAQ: Sedentary	26	12.96 (2.67)	34	11.46 (2.70)	-1.49 (-2.89 to -0.09)
	SIMPAQ: Walking	28	0.82 (0.68)	34	0.85 (0.91)	0.04 (-0.37 to 0.44)
	SIMPAQ: Exercise	27	0.08 (0.16)	34	0.33 (0.47)	0.25 (0.07 to 0.42)
	SIMPAQ: Other	27	0.75 (1.05)	34	1.15 (1.71)	0.4 (-0.31 to 1.11)
	EQ-5D-5L	28	0.75 (0.20)	34	0.76 (0.22)	0.01 (-0.10 to 0.12)
	SF-12 (PCS)	28	48.53 (11.51)	34	48.21 (8.95)	-0.32 (-5.66 to 5.03)
	SF-12 (MCS)	28	38.75 (11.34)	34	43.26 (12.06)	4.51 (-1.44 to 10.47)
	ReQoL-10	27	24.78 (8.81)	34	26.47 (8.35)	1.69 (-2.76 to 6.14)
	ReQoL-20	27	49.30 (16.53)	34	52.24 (15.00)	2.94 (-5.27 to 11.15)
6 months	BMI (kg/m²)	22	33.0 (5.30)	32	31.9 (5.60)	-1.1 (-4.1 to 2.0)
	PHQ-9	22	9.05 (7.07)	32	6.56 (5.43)	-2.48 (-6.10 to 1.14)
	GAD-7	22	6.5 (5.71)	32	5.47 (4.15)	-1.03 (-3.91 to 1.85)
	SIMPAQ: Bed	22	10.45 (2.28)	32	9.97 (2.02)	-0.49 (-1.71 to 0.73)
	SIMPAQ: Sedentary	22	12.02 (2.20)	32	11.49 (2.15)	-0.53 (-1.75 to 0.69)
	SIMPAQ: Walking	22	0.79 (0.58)	32	0.99 (0.88)	0.20 (-0.20 to 0.60)
	SIMPAQ: Exercise	22	0.06 (0.15)	32	0.28 (0.84)	0.22 (-0.09 to 0.52)
	SIMPAQ: Other	22	0.68 (0.72)	32	1.27 (1.10)	0.60 (0.10 to 1.10)
	EQ-5D-5L	22	0.72 (0.23)	32	0.77 (0.20)	0.05 (-0.07 to 0.17)

SF-12 (PCS)	22	46.57 (9.13)	32	48.26 (10.38)	1.69 (-3.69 to 7.06)
SF-12 (MCS)	22	40.2 (12.56)	32	42.77 (13.25)	2.57 (-4.59 to 9.73)
ReQoL-10	21	24.29 (8.67)	32	26.91 (8.16)	2.62 (-2.18 to 7.42)
ReQoL-20	21	49.76 (16.81)	32	53.25 (15.75)	3.49 (-5.81 to 12.79)