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CANWALK: A RANDOMISED FEASIBILITY TRIAL OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER

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ABSTRACT

Objectives: Walking is an adaptable, inexpensive and accessible form of physical activity. However its impact on quality of life and symptom severity in people with advanced cancer is unknown. This study aimed to assess the feasibility and acceptability of a randomised controlled trial (RCT) of a community-based walking intervention to enhance quality of life (QoL) in people with recurrent/metastatic cancer.

Design: We used a mixed-methods design comprising a two-centre RCT and nested qualitative interviews.

Participants: Patients with advanced breast, prostate, gynaecological or haematological cancers randomised 1:1 between intervention and usual care.

Intervention: The intervention comprised Macmillan's 'Move More' information, a short motivational interview with a recommendation to walk for at least 30 minutes on alternate days and attend a volunteer-led group walk weekly.

Outcomes: we assessed feasibility and acceptability of the intervention and RCT by evaluating study processes (rates of recruitment, consent, retention, adherence and adverse events), and using end of study questionnaires and qualitative interviews. Patient reported outcome measures (PROMS) assessing quality of life (QoL), activity, fatigue, mood and self-efficacy were completed at baseline and 6, 12 and 24 weeks.

Results: We recruited 42 (38%) of eligible participants. Recruitment was lower than anticipated (goal n=60), the most commonly reported reason being unable to commit to walking groups (n=19). Randomisation procedures worked well with groups evenly matched for age, sex and activity. By week 24, there was a 45% attrition rate. Most

PROMs whilst acceptable were not sensitive to change and did not capture key benefits.

Conclusions: The intervention was acceptable, well tolerated and the study design was judged acceptable and feasible. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. Consequently, an effectiveness RCT is warranted, with some modifications to the intervention to include greater tailoring and more appropriate PROMs selected.

(297 words)

Trial registration

ISRCTN42072606

Strengths and limitations of this study

- The study assessed the feasibility and acceptability of a randomised control trial (RCT) of community-based walking for people with recurrent or metastatic breast, gynecological, haematological or prostate cancers.
- The intervention made use of freely-available walking groups and information, combined with a brief motivational interview and recommendation to walk for at least 30 minutes on alternate days and attend a weekly walking group.
- A mixed-methods design, including a two-centre RCT with nested qualitative interviews, was used to assess feasibility and acceptability of the intervention *and* RCT, and test the utility of different patient report outcome measures (PROMS).
- The recruitment centres were London-based limiting generalisability.

- Views of participants from Black and ethnic minority patients were underrepresented as the majority of participants were Caucasian and English speaking.

INTRODUCTION

Life expectancy of people with recurrent or metastatic cancer is increasing but this patient group is at considerable risk of experiencing psychological [1] and physical health problems.[2,3] Despite growing evidence of significant health benefits, physical activity declines considerably during cancer treatment and remains low afterwards.[4] There is some evidence that maintaining or increasing physical activity in cancer patients can enhance QOL and well-being as disease progresses.[5,6] However, activity-based interventions are typically supervised and require attendance at specialist facilities, potentially limiting acceptability and economic sustainability. [5,7]

Brisk walking is an adaptable, inexpensive and effective physical activity [8,9] that has been shown to improve QoL, physical functioning and fatigue.[5,7] It can be undertaken alone or in groups and is not restricted to specific facilities or settings – a factor associated with longer-term behaviour change.[10] However, it is unclear whether walking is acceptable to, or improves physical and psychological wellbeing of, people with recurrent or metastatic cancer. We therefore assessed the feasibility and acceptability of a randomised controlled trial (RCT) of community-based walking for people with recurrent or metastatic cancer. Detailed methods have been published elsewhere.[11] This article reports on: acceptability and feasibility of the study design and intervention, and provides preliminary evidence of efficacy.

MATERIALS AND METHODS

Study design and participants

Feasibility of using RCT methodology to test the effectiveness of the walking intervention was assessed using a sequential, explanatory mixed-methods design[12] with nested qualitative interviews. The study was undertaken between April and November 2014 in two London NHS Foundation Trusts.

We aimed to recruit at least 60 patients, as recommended for feasibility trials.[13,14] Eligible participants were: i) ≥ 16 years; ii) diagnosed with recurrent or metastatic breast, colorectal, upper gastrointestinal, gynaecological, haematological, head and neck, melanoma or prostate cancer (specific diagnosis inclusion/exclusion criteria published elsewhere[11]).

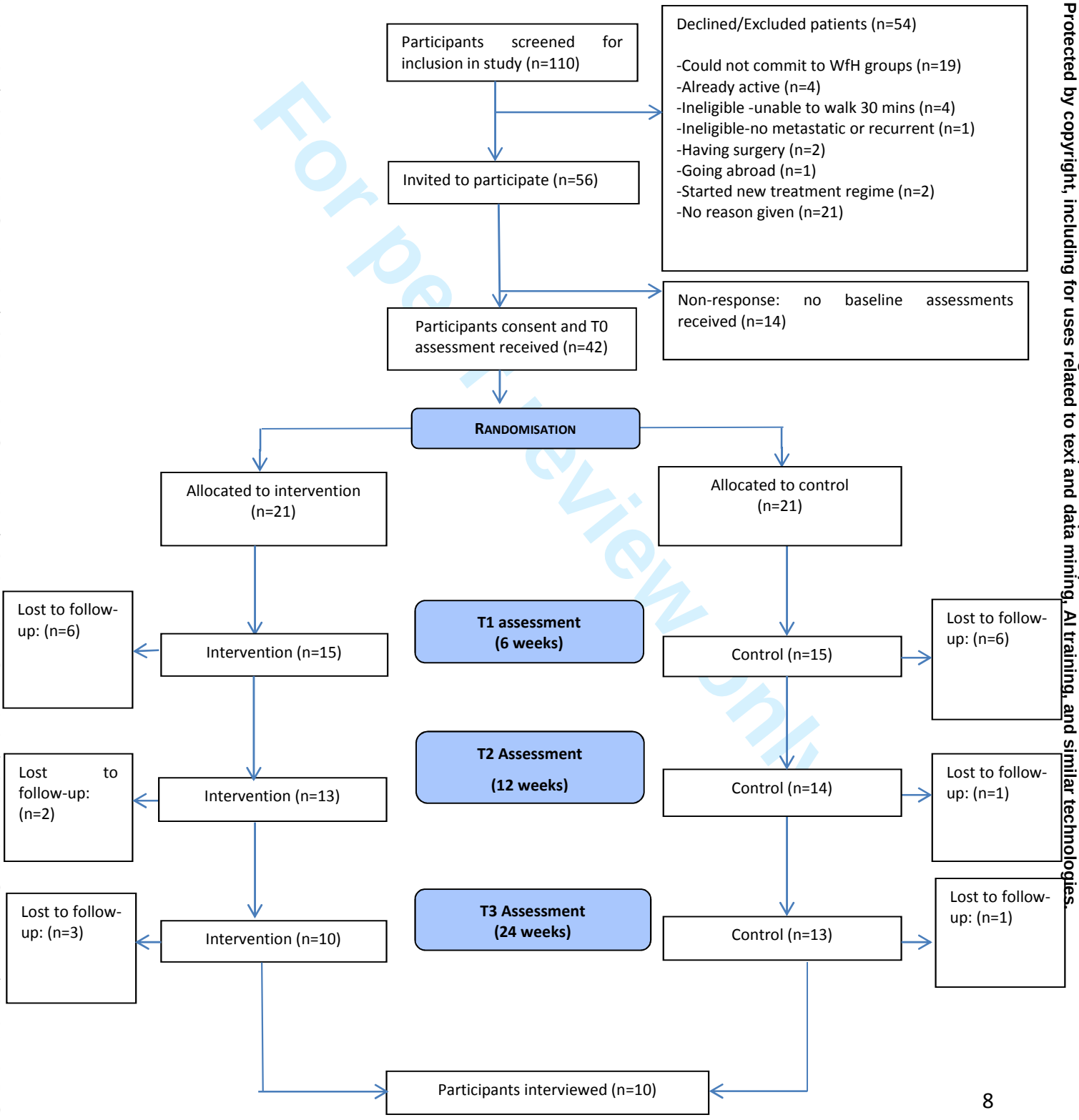
Recruitment and randomisation

Initially, healthcare professionals approached potential participants; however, recruitment was lower than expected; therefore, research staff were assigned to recruit. Participants completed postal questionnaires at baseline (T0), 6 (T1), 12 (T2) and 24 (T3) weeks following recruitment (see Figure 1). Additionally, those in the intervention group were asked to record their Walking for Health participation- including date and location of walks attended- on a simple form.

Consenting participants completed baseline questionnaires before randomisation. They were allocated, via an online automated system, to either the control (standard care) or

intervention group using minimisation on the basis of age (≤65, ≥66 years), sex (male, female) and baseline activity level (<1 hour /week, ≥1 hour/week).

Figure 1. Flow of participants through the study



Physical activity intervention

The 12-week *CanWalk* intervention aimed to motivate participants to walk for *at least* 30 minutes on alternate days. This target was selected as an acceptable minimum for those who may be sedentary and/or have reduced physical functioning. A 15-minute motivational telephone interview, promoting physical activity, was provided by VT or JH. Participants were additionally provided with printed material promoting activity, (Macmillan Cancer Support (MCS) 'Move More' booklet)[15] and encouraged to attend a weekly group walk of their choice from the *Walking for Health* (WfH) programme. WfH is a UK-wide network of free walking groups funded by Macmillan Cancer Support and hosted by The Ramblers, suitable for people living with long-term condition.[16] The control group were asked to continue with their usual activities.

Primary outcomes: Feasibility measures

Data were collected on rates of recruitment, consent, retention and adverse events. Reasons for non-participation and withdrawal were collected, where possible. Participants completed an end of study questionnaire (ESQ) assessing acceptability of CanWalk, randomisation process, study methods and outcome measures. Adherence to CanWalk was evaluated over 7-days at each assessment using a self-report measure. We assessed the feasibility of capturing objective data on walking behaviour by randomly allocating 50% of the control and intervention groups to use a pedometer (Omron HJ-321-E). Participants were asked to wear them for seven consecutive days at each time-point and complete a usage log recording their daily step count. Additionally, the intervention group was asked to keep a log of WfH walks they undertook.

Ten participants (5 per group; 6 men and 4 women; 5 >65 years; 9 White British or Irish) took part in semi-structured telephone interviews exploring the acceptability of CanWalk, randomisation process and outcome measures.

Secondary outcomes: Between group outcomes

Outcome measures for assessing efficacy of the intervention included quality of life (the primary RCT outcome measure), physical activity, mood, exercise self-efficacy, fatigue and performance status (the secondary RCT outcome measures).[11]

Data analysis

We examined differences between the baseline characteristics of those who completed or withdrew from the study using chi-square and *t*-tests, as appropriate. Descriptive statistics for all between group outcome measures are presented including means (SD), medians (interquartile range) and frequencies. Cohen's d with 95% confidence intervals (95% CI) was calculated for effect size. The mean (SD) for the main outcome (QoL) was used to estimate sample size for the effectiveness trial. All data were analysed using SPSS (v21) or SAS (v9.4).

Audio recordings of qualitative interviews were transcribed verbatim and analysed using the framework approach.[17] Descriptive analysis was undertaken of the ESQ and free-text comments integrated with the qualitative data. Findings from the qualitative and quantitative analyses are presented concurrently. The study design is reviewed using

the ADePT framework(a process for decision-making after pilot and feasibility trials)[18] (Appendix 1).

Ethical Approval

Ethical approval was gained from the National Research Ethics Service (Ref: 13/NW/0860) and research governance approval granted by both NHS Trusts.

RESULTS

Feasibility assessment

Recruitment

One hundred and ten people were eligible to participate; 49 (47%) declined - primarily because of work commitments. Although willing to walk on alternate days, they could not commit to a weekly walking group. Whilst initial interest in participating was relatively high (53%), the recruitment rate was lower (40%). Reasons for this are unknown. In interviews, participants reported the randomisation process was acceptable with 21 allocated to each group. Whilst there was little difference in most of the demographic and clinical characteristics between the groups (Table 1), almost half of the sample was educated to at least degree level - higher than would be expected in the general population.

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Men			
Mean age (SD)	66.2 (10.2)	65 (11.7)	65.6 (10.8)
Median age (range)	*68 (50-79)*	*71 (40-80)*	*69 (40-80)*
N	*10 (48)*	*11(52)*	*21*
Women			
Mean age (SD)	58 (11.6)	60 (12.2)	59(11.6)
Median age (range)	*59 (35-79)*	*59 (38-78)*	*59 (35-79)*
N	*11(52)*	*10(48)*	*21*
Ethnic origin	**N (%)**	**N (%)**	**N (%)**
White	17 (81)	17 (81)	34 (81)
Black	4 (19)	1 (5)	5 (12)
Other ethnic groups	0	2 (9)	2 (4)
Marital status			
Married	12 (57)	16 (80)	28 (68)
Widowed	0 (0)	1 (5)	1 (2)
Divorced/separated	4 (19)	1 (5)	5 (12)
Single	5 (24)	2 (10)	7 (17)
Marital status			
Married	12 (57)	16 (80)	28 (68)
Widowed	0 (0)	1 (5)	1 (2)
Divorced/separated	4 (19)	1 (5)	5 (12)
Single	5 (24)	2 (10)	7 (17)
Not answered	0	1	1
Employment status Employed (full or part-time)	4 (20)	6 (29)	10 (24)
Sick leave	3 (15)	2 (10)	5 (22)
Retired	10 (50)	10 (48)	20 (49)
Unemployed	2 (10)	3 (14)	5 (12)
Disabled and unable to work	1 (5)	0 (0)	1 (2)
Highest educational attainment GCSE/O Levels or equivalent	4 (20)	5 (25)	9 (23)
A Levels or equivalent	1 (5)	5 (25)	6 (15)
Degree/higher degree	12 (60)	7 (35)	19 (48)
No formal qualifications	3 (15)	3 (15)	6 (15)
Owner-occupier of housing	18 (86)	17 (81)	35 (83)
Has any caring responsibilities	3 (15)	1 (5)	4 (10)
Primary cancer			
Breast	4 (19)	3 (14)	7 (17)
Colorectal	0 (0)	5 (1)	1 (2)
Gynaecological	4 (19)	5 (24)	9 (21)
Haematological	4 (19)	5 (24)	9 (21)
Prostate	8 (38)	7 (33)	15 (36)

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Upper GI	1 (5)	0 (0)	1 (2)
Number of years since diagnosis Less than 1 year	6 (29)	4 (21)	10 (25)
1-2 years	8 (38)	6 (32)	14 (35)
3-4 year	2 (10)	2 (10)	4 (10)
5-9 year	4 (20)	4 (21)	8 (20)
10 years or more	1 (5)	3 (16)	4 (10)
Previous treatments for cancer[1] Surgery	8 (38)	8 (42)	16 (40)
Radiotherapy	8 (40)	10 (53)	18 (46)
Chemotherapy	14 (67)	11 (55)	25 (61)
Other	10 (59)	10 (53)	25 (61)
On-going cancer treatment	16 (76)	17 (81)	33 (79)
Any longstanding illness or disability[3]	9 (50)	4 (20)	13 (31)
Main hospital Site 1 Site 2	15 6	15 6	30 (71) 12 (29)

[1] Self-reported treatments, categories are not mutually exclusive

[2] Self-reported whether receiving on-going cancer treatment

[3] Self-reported whether any longstanding illnesses or disabilities

Retention

Nineteen participants (45%) withdrew from the study: 12 (28%) between T0 and T1; and seven (17%) between T2 and T3 (Figure 1). Although in general reasons for withdrawal were not provided, some patients were too unwell and two participants died during the study. The only factor associated with withdrawal was higher baseline anxiety (M= 6.4, SD = 8.1) compared to those who completed the study (M= 4.2, SD = 3.8) (t (40) = 1.16, p = 0.001).

Acceptability of outcome measures

In interviews, participants reported taking 10-40 minutes to complete outcome measures. All were judged appropriate except the Scottish Physical Activity Questionnaire (SPAQ). Eight participants reported it was repetitive and difficult to complete as illustrated below:

> *The SPAQ section… a lot of licking my fingers and sticking it in the air, lots of 'think of a number' type thing, it was hard to think. A pre-warning of what was going to be required might have been helpful so you could fill this section in accurately. (3013, male, prostate cancer)*

These problems were reflected in data quality, with 45% completing the daily activity data incorrectly or not at all. Further, insufficient numbers of participants returned the pedometer data at all assessments to permit analysis.

Assessment of methodological components of the trial

Application of the ADePT framework[18] suggests most components of the trial protocol worked well (Appendix 1). The only exception was participants were not recruited from three tumour groups: head and neck, colorectal and skin.

Safety and engagement with the intervention

No adverse outcomes or events were reported. Views about CanWalk were positive from the ESQ and interviews, although interview data suggested engagement with, and

adherence to, WfH group walks varied. Most (4/5) interviewees from the intervention group participated in WfH group walks plus self-initiated walks. One completed self-initiated walks only.

Hawthorne Effect

During interview, only one participant in the control group reported receiving information about exercise over the course of the study. Yet on the ESQ, 9 out of 12 said taking part in this study had stimulated them to undertake more physical activity. Interview findings confirmed this effect in three of the five control group members:

> *I found it all quite motivating as after filling in the questionnaire and using the pedometer I found that I was more focused on walking. I even did a long walk with the Ramblers which I haven't done in a while. It prompted me to be more fit. I sit less on the sofa now and try to get myself outside. (5020, female, haematological cancer with pedometer)*

Participants' views on the intervention

At 24-weeks, nine participants completed the ESQ and results indicated that most (n=8) found it useful and were satisfied (n=7). Nevertheless, a number of barriers to the intervention were identified at interview. Some participants preferred self-initiated walking, and felt WfH groups, while beneficial for some, did not suit everybody. Reasons included dislike of group activities and accessibility issues. One younger participant who withdrew from the study felt the group walks were more appropriate for

older people and decided to continue with self-initiated walks only. Consequently, some interviewees suggested modifying the intervention to offer alternative options to the group walks.

Between group outcomes

Primary RCT outcome: Quality of life

Whilst at baseline the control group reported lower median FACT-G (Functional Assessment of Cancer Therapy- General) QoL scores than the intervention (53 vs 58, respectively), scores were comparable during follow-up (Table 2). Likewise the FACT-G sub-scales scores at T1-T3 were relatively high and stable for both intervention and control groups (Table 2).

Table 2
Primary outcome measure for possible RCT by assessment time and study group

Quality of life	Study group	Baseline Mean (SD) *Median (IQR)*	6 week Mean (SD) *Median (IQR)*	12 week Mean (SD) *Median (IQR)*	24 week Mean (SD) *Median (IQR)*
FACT-G[a] Total score[19]	**Control**	52 (9.1) *53 (11.0)*	51 (11.2) *56(17.5)*	50 (7.9) *52 (13.0)*	48 (12.7) *54 (20.0)*
	Intervention	57 (5.2) *58 (4.0)*	56(6.3) *57 (7.25)*	55 (5.5) *56 (4.0)*	57 (6.9) *56 (10.5)*
Cohen's d effect size (95% CI)		0.67 (0.04,1.28)	0.55 (-0.19, 1.26)	0.73 (-0.07, 1.49)	0.79 (-0.09, 1.62)
Physical well-being sub-scale	**Control**	22(5.8) *24(7.0)*	21 (5.7) 21 (10.5)	22 (5.7) *25 (11.0)*	23 (4.5) *24 (7.5)*
	Intervention	23(4.7) *26 (6.0)*	25(2.4) 26 (4)	25 (3.3) *26 (6.0)*	23 (4.7) *25 (4.7)*

Cohen's d effect size (95% CI)		0.19 (-0.42, 0.79)	0.91 (0.14, 1.64)	0.64 (-0.15, 1.39)	0.00 (-0.82, 0.82)
Social and family well-being sub-scale	**Control**	20 (6.1) *21 (11)*	19 (7.0) 21(10.75)	19 (6.2) *19 (10.0)*	18 (7.3) *20 (12.5)*
	Intervention	22(3.6) *23 (6.0)*	22 (3.9) *23 (6.0)*	22 (4.0) *23 (4.0)*	22 (5.5) *23 (8.0)*
Cohen's d effect size (95% CI)		0.40 (-0.22, 1.00)	0.53 (-0.21, 1.24)	0.57 (-0.22, 1.32)	0.61 (-0.26, 1.43)
Emotional well-being sub-scale	**Control**	17 (5.2) *16 (8.0)*	18 (4.4) *19 (5.3)*	19 (3.8) *19 (6.0)*	20 (3.3) *20 (6.5)*
	Intervention	17 (5.5) *19 (7.0)*	20 (3.6) *20 (4.0)*	20 (3.7) *21 (6.0)*	18 (3.8) *18 (6.2)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	0.50 (-0.24, 1.21)	0.27 (-0.50, 1.02)	-0.57 (-1.39, 0.29)
Functional well-being sub-scale	**Control**	18(5.0) *19 (9.0)*	17 (6.6) *17.5 (10.3)*	19 (6.5) *19 (11.0)*	21 (7.6) *23 (14.5)*
	Intervention	21(6.5) *23 (13.0)*	23(5.6) *26 (8.0)*	23 (4.7) *23 (7.0)*	23 (5.3) *25 (8.0)*
Cohen's d effect size (95% CI)		0.52 (-0.11, 1.12)	0.98 (0.20, 1.71)	0.70 (-0.10, 1.46)	0.30 (-0.54, 1.12)

[a] FACT, Functional Assessment of Cancer Therapy- General

Secondary RCT outcomes

Comparable results for both groups were also found for the secondary outcomes with median scores remaining relatively stable across assessments. Detailed descriptive analysis of subscale scores provide evidence of some floor or ceiling effects (data not

shown). For instance, the EQ-5D (health status) showed a clear floor effect with most participants reporting few symptoms at each time point.

The GPPAQ physical activity index (PAI), which includes activity at work, physical exercise and cycling (but not walking), indicated the intervention group was more active at all assessments than the control, and physical activity levels for both groups declined over the study period. However, the GPPAQ item which measures walking activity indicated that the proportion of participants doing at least 3-hours of walking a week increased in both groups (Table 3).

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
Global fatigue score[20]	**Control**	36(21.6) *31 (28.0)*	35 (22.0) *43 (37.0)*	32 (21.9) *26 (40.0)*	28 (24.5) *18 (47.5)*
	Intervention	32 (22.3) *33(43.0)*	18 (15.9) *15 (24.0)*	23 (17.3) *25 (33.0)*	29 (19.1) *31 (24.7)*
Cohen's d effect size (95% CI)		-0.18 (-0.78, 0.43)	-0.89 (-1.61, -0.11)	-0.45 (-1.20, 0.32)	0.04 (-0.78, 0.87)
Exercise self-efficacy[21]	**Control**	28 (6.0) *29(9.0)*	29 (5.5) *29 (6.0)*	29 (4.6) *30 (6.0)*	29 (5.0) *28 (4.5)*
	Intervention	30 (6.0) *31 (8.0)*	33 (5.2) *33 (10.0)*	33 (5.4) *36 (10.0)*	34 (4.6) *34 (8.25)*
Cohen's d effect size (95% CI)		0.33 (-0.28, 0.94)	0.75 (-0.01, 1.71)	0.80 (-0.01, 1.56)	1.01 (0.10, 1.84)
Stress total score[22]	**Control**	9(9.0) *6(12.0)*	8 (9.1) *5 (9.5)*	4 (4.7) *4 (8.0)*	9 (9.5) *8 (0-26)*
	Intervention	8(9.7) *2 (18.0)*	4 (5.1) *4 (6.0)*	5 (5.9) *4 (10.0)*	3 (3.6) *2 (6.0)*
Cohen's d effect size (95% CI)		-0.11 (-0.71, 0.50)	-0.54 (-1.26, 0.20)	0.19 (-0.57, 0.94)	-0.76 (-1.59, 0.11)
Anxiety total score[22]	**Control**	6(5.3) *6(6.0)*	5 (5.4) *4 (6.5)*	3 (3.1) *2 (6.0)*	6 (8.3) *2 (9.0)*
	Intervention	4 (7.1) *2 (4.0)*	2 (3.3) *0 (2.0)**	4 (6.0) *2 (4.0)*	2 (2.7) *0 (5.0)*
Cohen's d effect size		-0.32	-0.67	0.21	-0.60

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
(95% CI)		(-0.92, 0.30)	(-1.39, 0.08)	(-0.55, 0.96)	(-1.42, 0.26)
Depression total score[22]	**Control**	8(7.2) *6 (11.0)*	8 (8.4) *2 (14.0)*	5 (6.5) *2 (9.0)*	8 (9.0) *2 (13.0)*
	Intervention	8(10.1) *6 (15.0)*	3 (4.9) *0 (4.0)**	4 (5.9) *0 (6.0)*	4 (5.7) *2 (9.0)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	-0.73 (-1.43, 0.03)	-0.16 (-0.91, 0.60)	-0.52 (-1.33, 0.34)
EQ-5D score[23]	**Control**	2 (0.66) *2 (1.0)*	2 (0.5) *2 (1.0)*	2 (0.6) *1 (1.0)*	1 (0.5) *1 (0.7)*
	Intervention	1 (0.52) *1 (1.0)*	1 (0.4) *1 (0.8)*	1 (0.4) *1 (1.0)*	1 (0.4) *1 (0.6)*
Cohen's d effect size (95% CI)		-1.68 (-2.35, -0.95)	-2.21 (-3.05, -1.25)	-1.95 (-2.80, -0.98)	0.00 (-0.82, 0.82)
EQ-VAS Your health today score out of 100[23]	**Control**	72 (22.6) *80 (40)*	82 (12.1) *78 (20.3)*	76 (26.4) *90 (41.5)*	79 (19.6) *80 (31.0)*
	Intervention	75 (17.0) *70 (30)*	84 (12.8) *85 (20.0)*	78 (18.1) *80 (28.8)*	81 (14.9) *80 (25.0)*
Cohen's d effect size (95% CI)		0.15 (-0.46, 0.75)	0.16 (-0.56, 0.87)	0.09 (-0.67, 0.84)	0.17 (-0.67, 0.99)
Active/ moderately active[24]		**N (%)**	**N (%)**	**N (%)**	**N (%)**
	Control	2 (10)	0	1(7)	0
	Intervention	6(29)	5 (34)	4 (31)	2(20)
Walked 3 ≥ hours in last 7days[24]	**Control**	9 (47)	7 (54)	11 (79)	9 (82)
	Intervention	9 (43)	9 (70)	7 (58)	5 (62)

In contrast, interview data showed that the intervention group felt that they benefited in terms of physical, emotional and psychological, social wellbeing and lifestyle changes (see Table 4 for illustrative quotes). Most participants reported being previously active and understood the benefits of being more physically active. On the ESQ, 7 out of 10 of the intervention group reported they had set physical activity goals at baseline which

they achieved by 24-weeks. In interviews, all participants in the intervention group and 3 out of 5 in the control group reported being more active by 24-weeks.

Wellbeing and lifestyle benefits, such as weight loss, also motivated participants to increase the amount they walked. They spoke about how it improved their overall quality of life and helped them maintain a positive attitude towards their illness. Many participants in the intervention group spoke of the social benefits of participating in the WfH groups (Table 4 for illustrative quotes).

Table 4 Participants views and experiences of the intervention

Theme	Illustrative comments
Physical benefits	*Its praises should be sung more widely, it really would deserve that. It had a revolutionary effect on me. I'm a walking bore now I'm afraid! It was just the right thing at just the right time for me. I think more about walking now, I think can I walk there instead of catching the bus. It's a fairly painless way of keeping weight down while still eating a little bit of what you enjoy….* (3022 male, prostate cancer no pedometer) *I have walked ever since at least 3 days a week. This study has stimulated me. I drop my daughter off at school then go with the dog for a long walk. I have noticed the difference physically. I am back on chemo now and have noticed differences with side effects compared to last year. Last year I had oedema which I don't this time and I just feel a lot fitter this time round. In general, I have a little more stamina than before.* (5016, male, haematological cancer, with pedometer)
Emotional/ Psychological wellbeing	*I would definitely recommend it, particularly to people who are not actively sporty or for sedentary people. Being diagnosed with cancer is a pretty devastating thing and being told its terminal is even more devastating and when I'm on the walks I forget about the cancer, they have helped me enormously by keeping me physically fit and keeping me well but also mentally. I bang on a lot less to those around me about dying than I used to. And that's got to be good for them as well.* (3022, male prostate cancer)
Social benefits	*I have been doing Nordic walking [WfH] at least once a week - it has made a huge difference to me physically and mentally. It makes me do more than I would if I was walking on my own, I have met all sorts of people and as I live on my own it's great being out and meeting other people.* (4065, female gynaecological cancer with pedometer)
Wellbeing	*The impact has been immense! Gave me the motivation to not only*

Table 4 Participants views and experiences of the intervention	
Theme	Illustrative comments
and lifestyle benefits	*increase walking activity from minute to 3-4 hours per week but also to reduce weight to desired 77-80kg by altering diet/ reducing sweets/sugars. Great boost to morale-no longer dwell on being terminal - just on getting on with making life as enjoyable as possible, greatly helped by friends made on regular 'walks for life'.* (3022, male, prostate cancer)
Barriers to group walks	*There was only one walk I could find locally that lasted more than 30 mins and seemed to cover a reasonable distance. I turned up to meet and they were meeting in the tea room. I know this sounds a bit ridiculous but I wanted to see who was in the group rather than going straight in. It seemed that everyone in the group was quite a bit older than me, and they spent the first 20mins of the walking time drinking tea in the cafe. When they moved off they were walking quite slowly. I'm not criticising the validity of these social group walks but I was looking for something a bit more energetic, and with people closer in age to me* (8003, male, colorectal cancer).

DISCUSSION

This study aimed to assess the feasibility and acceptability of a RCT of a community-based walking programme in people with recurrent/metastatic cancer. Our results indicate that most self-initiated walks were acceptable, though some reported being unable to commit to the WfH groups regularly, largely due to work commitments. The CanWalk intervention, based on the UK's NICE (National Institute for Healthcare and Clinical Excellence) guidance for promoting physical activity,[25,26] includes active components identified as helping individuals change their behaviour,[27] such as goal setting, planning and social support. However, it is possible that including more monitoring and tailored feedback could be beneficial and could be offered remotely through the use of apps and/or websites. This is supported by comments from participants from both the intervention and support groups indicating they found

completing the outcome measures stimulated them to increase their physical activity levels.

Key elements of feasibility testing have been identified by Bowen et al (2009)[28] and are used (highlighted in bold) here to evaluate whether the CanWalk intervention warrants further investigation. A central focus to our study involved estimating **demand** for the intervention. Forty per cent of those eligible to participate in the study consented. This is comparable to recruitment rates reported in similar studies[29] and not unexpected in a population comprising people with advanced cancer. Almost a third withdrew within 6-weeks and preliminary evidence indicated an association with higher baseline anxiety. This warrants further exploration and consideration of ways the intervention could be made more appealing and acceptable for people with symptoms of anxiety, perhaps through a buddy system or by enhancing the motivational interview component with 'booster' follow-up sessions.

This feasibility study also explored the **implementation** of the study and intervention. Importantly, based on the study data, a power calculation was performed for target recruitment for a future trial. However, the proposed recruitment estimate was not feasible within the timeframe; despite extending recruitment and widening the eligibility criteria to include other diagnoses.

For clinicians to change their practice, they require evidence of the **practicality** of the interventions ie that they can be delivered within existing means and resources.[28] The

complementary components of the intervention promoted physical activity. The researchers spent approximately 20-minutes per person delivering CanWalk. This suggests that if the intervention proves effective, it is could be sufficiently brief for delivery by health care professionals in the clinical setting.

Limited-efficacy testing gives an indication of the likely impact of the intervention, although not the primary aim of a feasibility study. Results suggest few differences between groups across the outcome measures at any time point. Arguably, this inability to detect change could be attributed to the small sample size, as the pilot study was insufficiently powered to detect subtle differences. Further, similar to other studies[30] contamination may have occurred whilst assessing activity levels using outcome measures which reportedly stimulated *all* participants to engage in physical activity. Likewise, participants highlighted that using pedometers with both groups had a similar effect. This suggests an alternative method of assessing walking behaviour is required.

Detailed descriptive evaluation of the performance of the outcome measures suggests that whilst being reliable, some of the measures may not be sensitive to change as they demonstrated floor/ceiling effects. Moreover, feedback from the ESQ and interviews suggested social support was a key perceived benefit of participating in the WfH walks, but this was not reflected in the FACT-G social wellbeing sub-scale scores. However this may be because it focuses entirely on support from family and relatives and so would not be sensitive to benefits from making wider social contacts. It will therefore be important to include a brief social support and engagement measure (such as the Duke-

Social Support Questionnaire)[31] in future research. Our findings demonstrate the importance of pilot testing questionnaires. As many participants reported the SPAQ was time consuming and confusing suggesting a need to use other measures of physical activity for both measuring adherence to the intervention and outcomes. Pedometer data were often not returned thus alternative methods for measuring the intensity, duration and frequency of physical activity in any future study are recommended. Whilst accelerometers have been used in previous studies they often require expert knowledge to interpret and analyse results, so the use of off-the-shelf wearable technologies may offer an alternative and more cost-effective approach.[32]

Some participants were, from the outset, already active which contributed to difficulty in detecting between group changes. Thus it may be preferable to only recruit people who are judged to be inactive. However, this will reduce the number eligible to participate and exclude people who, although active, wish to increase the amount they walk.

Based on the study findings a number of **adaptations** are proposed for a future study including the refinement of the study samples to include different comparison groups, for example, a tailored CanWalk intervention and written information only group. Furthermore, it will be important to ensure outcome measures used match the benefits reported by participants in the interviews, such as feeling fitter and having more stamina (e.g. functional walking/fitness tests such as incremental shuttle walk or 6-minute walk test; being less inactive (e.g. measure of sedentary behaviour), weight loss (e.g. weight, body mass index, hip to waist ratio) and symptom control.

Several limitations were identified in the study. The recruitment centres were London-based thus limiting generalisability. Further, the qualitative sample was small, limiting the extent of in-depth analysis of participants' perceptions and experiences. Another limitation is that the views of participants from Black and minority ethnic groups are underrepresented as the study recruited primarily Caucasian participants and English speakers.

Conclusions

This study investigated the feasibility and acceptability of undertaking a RCT of a community-based walking programme to enhance QoL in people with recurrent or metastatic cancer. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. However, further exploration of the intervention is required to refine and understand its components and enhance its capacity to create measurable change.

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Competing interest: The authors declare that they have no competing interests.

Contributorship statement: VT and JH recruit participants and were responsible for day-to-day study coordination, delivery of the intervention and drafted the manuscript. JA is the study chief investigator and provided the concept, hypotheses, study design and methods, recruitment of participants, is responsible for the overall study management and drafted and critically revised the manuscript. ER, MVH, AP, LM, JG and JF participated in the design of the study, critically revised the protocol and the manuscript. All authors read and approved the final manuscript.

Data Sharing: Please contact corresponding author for data sharing.

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Online supplementary information

Appendix 1
Summary of findings using ADePT methodological issues for feasibility research

Methodological issues	Findings	Evidence
1. Did the feasibility study allow a sample size calculation for the main trial?	Achieved	42 of the target of 60 participants achieved in feasibility study. 108 participants would need to be randomised to each group for the main trial.
2. What factors influenced eligibility and what proportion of those approached were eligible?	Mainly due to refusal to participate	Reasons provided included being: -unable to commit to WfH groups (n=19) -physically active already (n=4) -Ineligible -unable to walk 30 mins (n=4) -Ineligible-no metastatic or recurrent (n=1) -Having surgery (n=2) -Going abroad (n=1) -Started new treatment regime (n=2)
3. Was recruitment successful?	Recruitment was fairly successful.	42/105 screened participants. This is reasonable for a physical activity feasibility study including people with advanced and metastatic cancers.
4. Did eligible participants consent?	Consent of eligible participants was good.	42/56 patients who were provided with the baseline questionnaire and consent returned these.
5. Were participants successfully randomized and did randomization yield equality in groups?	Randomization procedures worked well and equality in groups for age and sex were achieved. However, the control group were far more active at baseline suggesting the minimisation criteria of walking 3 hours each week was not sensitive enough (because some participants engaged in other physical activity).	21 men and 21 women with comparable distribution between control and intervention. Mean and median age in both groups was comparable and representative of the target population. Equal numbers of participants in each group walked for at least 3 hours, however 6 of the control group were classed as 'active' compared with 2 in the intervention group.
6. Were the blinding procedures adequate?	Not applicable.	

Appendix 1 Summary of findings using ADePT methodological issues for feasibility research		
7. Did participants adhere to the intervention?	Adherence for those who were randomised to the intervention was good; however, some participants adapted the intervention.	Questionnaires and interviews. Participants took part in the walking groups during the 12 week period. Some continued with these groups and others continued to walk on their own or with friends/family
8. Was the intervention acceptable to the participants?	The intervention was mostly acceptable.	Questionnaires and interviews. Overall participants enjoyed taking part. One younger participant withdrew because he did not think the walking groups were age appropriate.
9. Was it possible to calculate intervention costs and duration?	Partially achieved.	The MI intervention lasted 10-15 minutes. Full costs should be included in future RCT.
10. Were outcome assessments completed?	Completion of outcome assessment was good between baseline and 12 weeks (intervention period). Attrition was more evident at 24 weeks.	Baseline: 42 questionnaires/ 14 pedometer logs completed 6 weeks: 30 questionnaires/ 11 pedometer logs completed 12 weeks: 27 questionnaires/ 9 pedometer logs completed 24 weeks: 23 questionnaires/ 8 pedometer logs completed
11. Were outcomes measured those that were the most appropriate?	Partially.	Although good internal reliability was indicated (Cronbach α >0.80) there was evidence of ceiling/floor effects. SPAQ was found to be unacceptable to participants with inadequate data quality.
12. Was retention to the study good?	After an initial withdrawal after randomisation 6 to 12 week retention was good. Retention was reasonable at 24 weeks for a physical activity feasibility study including people with advanced and metastatic cancers.	See outcome assessment above (10).
13. Were the logistics of running a multicentre trial assessed?	Some clinics were better at recruiting than others but both hospital sites recruited.	Feedback from site staff suggests that dedicated research nurses or researchers based at each hospital are recommended for the main RCT. Recruitment was easier when researchers attended all relevant clinics.

Appendix 1 Summary of findings using ADePT methodological issues for feasibility research		
14. Did all components of the protocol work together?	All components of the protocol worked well.	No difficulties identified in processes or implementation by the researchers or site staff (research nurses/clinicians).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Completed for CANWALK: A RANDOMISED FEASIBILITY TRIAL OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER.

Please note the feasibility/pilot RCT COSORT statement is not yet available and so we have completed the standard CONSORT checklist.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1, feasibility randomised trial
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	7 (note feasibility RCT)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7-8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	n/a
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8, 11
	13b	For each group, losses and exclusions after randomisation, together with reasons	8, 11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7, 8
	14b	Why the trial ended or was stopped	n/a (feasibility trial)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8,12
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-15, 19-21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21- 24, 25

Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

CANWALK: A FEASIBILITY STUDY WITH EMBEDDED RANDOMISED CONTROLLED TRIAL PILOT OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER

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Primary Subject Heading:	Oncology
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	feasibility studies, quality of life, walking, metastatic and recurrent cancer, randomised controlled trial

CANWALK: A FEASIBILITY STUDY WITH EMBEDDED RANDOMISED CONTROLLED TRIAL PILOT OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER

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ABSTRACT

Objectives: Walking is an adaptable, inexpensive and accessible form of physical activity. However its impact on quality of life and symptom severity in people with advanced cancer is unknown. This study aimed to assess the feasibility and acceptability of a randomised controlled trial (RCT) of a community-based walking intervention to enhance quality of life (QoL) in people with recurrent/metastatic cancer.

Design: We used a mixed-methods design comprising a two-centre RCT and nested qualitative interviews.

Participants: Patients with advanced breast, prostate, gynaecological or haematological cancers randomised 1:1 between intervention and usual care.

Intervention: The intervention comprised Macmillan's 'Move More' information, a short motivational interview with a recommendation to walk for at least 30 minutes on alternate days and attend a volunteer-led group walk weekly.

Outcomes: we assessed feasibility and acceptability of the intervention and RCT by evaluating study processes (rates of recruitment, consent, retention, adherence and adverse events), and using end of study questionnaires and qualitative interviews. Patient reported outcome measures (PROMS) assessing quality of life (QoL), activity, fatigue, mood and self-efficacy were completed at baseline and 6, 12 and 24 weeks.

Results: We recruited 42 (38%) of eligible participants. Recruitment was lower than anticipated (goal n=60), the most commonly reported reason being unable to commit to walking groups (n=19). Randomisation procedures worked well with groups evenly matched for age, sex and activity. By week 24, there was a 45% attrition rate. Most

PROMs whilst acceptable were not sensitive to change and did not capture key benefits.

Conclusions: The intervention was acceptable, well tolerated and the study design was judged acceptable and feasible. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. Consequently, an effectiveness RCT is warranted, with some modifications to the intervention to include greater tailoring and more appropriate PROMs selected.

(297 words)

Trial registration

ISRCTN42072606

Strengths and limitations of this study

- The study assessed the feasibility and acceptability of a randomised control trial (RCT) of community-based walking for people with recurrent or metastatic breast, gynecological, haematological or prostate cancers.
- The intervention made use of freely-available walking groups and information, combined with a brief motivational interview and recommendation to walk for at least 30 minutes on alternate days and attend a weekly walking group.
- A mixed-methods design, including a two-centre RCT with nested qualitative interviews, was used to assess feasibility and acceptability of the intervention *and* RCT, and test the utility of different patient report outcome measures (PROMS).
- The recruitment centres were London-based limiting generalisability.

- Views of participants from Black and ethnic minority patients were underrepresented as the majority of participants were Caucasian and English speaking.

INTRODUCTION

Life expectancy of people with recurrent or metastatic cancer is increasing but this patient group is at considerable risk of experiencing psychological [1] and physical health problems.[2,3] Despite growing evidence of significant health benefits, physical activity declines considerably during cancer treatment and remains low afterwards.[4] There is some evidence that maintaining or increasing physical activity in cancer patients can enhance QOL and well-being as disease progresses.[5,6] However, activity-based interventions are typically supervised and require attendance at specialist facilities, potentially limiting acceptability and economic sustainability. [5,7]

Brisk walking is an adaptable, inexpensive and effective physical activity [8,9] that has been shown to improve QoL, physical functioning and fatigue.[5,7] It can be undertaken alone or in groups and is not restricted to specific facilities or settings – a factor associated with longer-term behaviour change.[10] However, it is unclear whether walking is acceptable to, or improves physical and psychological wellbeing of, people with recurrent or metastatic cancer. We therefore assessed the feasibility and acceptability of a community-based walking for people with recurrent or metastatic cancer and randomised controlled trial (RCT). Detailed methods have been published elsewhere.[11] This article reports on: acceptability and feasibility of the study design and intervention, and provides preliminary evidence of efficacy.

MATERIALS AND METHODS

Study design and participants

Feasibility of using RCT methodology to test the effectiveness of the walking intervention was assessed using a sequential, explanatory mixed-methods design[12] with nested qualitative interviews. The study was undertaken between April and November 2014 in two London NHS Foundation Trusts.

We aimed to recruit at least 60 patients, in order to be able to estimate the standard deviation of the QoL outcome and estimation of the true treatment difference and perform a power calculation and sample size for the any future RCT [11] as recommended for feasibility trials.[13,14] Eligible participants were: i) ≥ 16 years; ii) diagnosed with recurrent (advancing) or metastatic breast, colorectal, upper gastrointestinal, gynaecological, haematological, head and neck, melanoma or prostate cancer (specific diagnosis inclusion/exclusion criteria published elsewhere[11]).

Recruitment and randomisation

Initially, healthcare professionals (HCP) approached potential participants; however, because HCP were mostly too busy to identify patients, recruitment was lower than expected; therefore, research staff were assigned to recruit. Participants completed postal questionnaires at baseline (T0), 6 (T1), 12 (T2) and 24 (T3) weeks following recruitment (see Figure 1). Additionally, those in the intervention group were asked to record their Walking for Health participation- including date and location of walks attended- on a simple form.

Consenting participants completed baseline questionnaires before randomisation. They were allocated, via an online automated system, to either the control (standard care) or intervention group using minimisation on the basis of age (≤65, ≥66 years), sex (male, female) and baseline activity level (<1 hour /week, ≥1 hour/week).

Physical activity intervention

The 12-week *CanWalk* intervention aimed to motivate participants to walk for *at least* 30 minutes on alternate days. This target was selected as an acceptable minimum for those who may be sedentary and/or have reduced physical functioning. A 15-minute motivational telephone interview, promoting physical activity, was provided (by authors VT or JH). Participants were additionally provided with printed material promoting activity, (Macmillan Cancer Support (MCS) 'Move More' booklet)[15] and encouraged to attend a weekly group walk of their choice from the *Walking for Health* (WfH) programme. WfH is a UK-wide network of free walking groups funded by Macmillan Cancer Support and hosted by The Ramblers, suitable for people living with long-term condition.[16] Full details are published elsewhere.[11] The control group were asked to continue with their usual activities.

Primary outcomes: Feasibility measures

Data were collected on rates of recruitment, consent, retention and adverse events. Reasons for non-participation and withdrawal were collected, where possible. Participants completed an end of study questionnaire (ESQ) assessing acceptability of CanWalk, randomisation process, study methods and outcome measures. Adherence

to CanWalk was evaluated over 7-days at each assessment using a self-report measure. We assessed the feasibility of capturing objective data on walking behaviour by randomly allocating 50% of the control and intervention groups to use a pedometer (Omron HJ-321-E). Participants were asked to wear them for seven consecutive days at each time-point and complete a usage log recording their daily step count. Additionally, the intervention group was asked to keep a log of WfH walks they undertook. Where possible, reasons for withdrawal from the study were collected.

Ten participants (5 per group; 6 men and 4 women; 5 >65 years; 9 White British or Irish) took part in semi-structured telephone interviews exploring the acceptability of CanWalk, randomisation process and outcome measures.

Secondary outcomes: Between group outcomes

Outcome measures for assessing efficacy of the intervention included quality of life (the primary RCT outcome measure), physical activity, mood, exercise self-efficacy, fatigue and performance status (the secondary RCT outcome measures).[11]

Data analysis

We examined differences between the baseline characteristics of those who completed or withdrew from the study using chi-square and *t*-tests, as appropriate. Descriptive statistics for all between group outcome measures are presented including means (SD), medians (interquartile range) and frequencies. Cohen's d with 95% confidence intervals (95% CI) was calculated for effect size. The mean (SD) for the main outcome (QoL) was

used to estimate sample size for the effectiveness trial. All data were analysed using SPSS (v21) or SAS (v9.4).

Audio recordings of qualitative interviews were transcribed verbatim and analysed using the framework approach.[17] Descriptive analysis was undertaken of the ESQ and free-text comments integrated with the qualitative data. Findings from the qualitative and quantitative analyses are presented concurrently. The study design is reviewed using the ADePT framework(a process for decision-making after pilot and feasibility trials)[18] (Appendix 1).

Ethical Approval

Ethical approval was gained from the National Research Ethics Service (Ref: 13/NW/0860) and research governance approval granted by both NHS Trusts.

RESULTS

Feasibility assessment

Recruitment

One hundred and ten people were eligible to participate; 49 (47%) declined - primarily because of work commitments. Although willing to walk on alternate days, they could not commit to a weekly walking group. Whilst initial interest in participating was relatively high (53%), the recruitment rate was lower (40%). Reasons for this are unknown. In interviews, participants reported the randomisation process was acceptable with 21 allocated to each group. Whilst there was little difference in most of the

demographic and clinical characteristics between the groups (Table 1), almost half of the sample was educated to at least degree level - higher than would be expected in the general population.

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Men			
Mean age (SD)	66.2 (10.2)	65 (11.7)	65.6 (10.8)
Median age (range)	*68 (50-79)*	*71 (40-80)*	*69 (40-80)*
N	*10 (48)*	*11(52)*	*21*
Women			
Mean age (SD)	58 (11.6)	60 (12.2)	59(11.6)
Median age (range)	*59 (35-79)*	*59 (38-78)*	*59 (35-79)*
N	*11(52)*	*10(48)*	*21*
Ethnic origin	**N (%)**	**N (%)**	**N (%)**
White	17 (81)	17 (81)	34 (81)
Black	4 (19)	1 (5)	5 (12)
Other ethnic groups	0	2 (9)	2 (4)
Marital status			
Married	12 (57)	16 (80)	28 (68)
Widowed	0 (0)	1 (5)	1 (2)
Divorced/separated	4 (19)	1 (5)	5 (12)
Single	5 (24)	2 (10)	7 (17)
Employment status Employed (full or part-time)	4 (20)	6 (29)	10 (24)
Sick leave	3 (15)	2 (10)	5 (22)
Retired	10 (50)	10 (48)	20 (49)
Unemployed	2 (10)	3 (14)	5 (12)
Disabled and unable to work	1 (5)	0 (0)	1 (2)
Highest educational attainment GCSE/O Levels or equivalent	4 (20)	5 (25)	9 (23)
A Levels or equivalent	1 (5)	5 (25)	6 (15)
Degree/higher degree	12 (60)	7 (35)	19 (48)
No formal qualifications	3 (15)	3 (15)	6 (15)
Owner-occupier of housing	18 (86)	17 (81)	35 (83)
Has any caring responsibilities	3 (15)	1 (5)	4 (10)
Primary cancer			
Breast	4 (19)	3 (14)	7 (17)
Colorectal	0 (0)	5 (1)	1 (2)

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Gynaecological	4 (19)	5 (24)	9 (21)
Haematological	4 (19)	5 (24)	9 (21)
Prostate	8 (38)	7 (33)	15 (36)
Upper GI	1 (5)	0 (0)	1 (2)
Number of years since diagnosis Less than 1 year	6 (29)	4 (21)	10 (25)
1-2 years	8 (38)	6 (32)	14 (35)
3-4 year	2 (10)	2 (10)	4 (10)
5-9 year	4 (20)	4 (21)	8 (20)
10 years or more	1 (5)	3 (16)	4 (10)
Previous treatments for cancer[1] Surgery	8 (38)	8 (42)	16 (40)
Radiotherapy	8 (40)	10 (53)	18 (46)
Chemotherapy	14 (67)	11 (55)	25 (61)
Other	10 (59)	10 (53)	25 (61)
On-going cancer treatment[2]	16 (76)	17 (81)	33 (79)
Any longstanding illness or disability[3]	9 (50)	4 (20)	13 (31)
Main hospital			
Site 1	15	15	30 (71)
Site 2	6	6	12 (29)

[1] Self-reported treatments, categories are not mutually exclusive

[2] Self-reported whether receiving on-going cancer treatment

[3] Self-reported whether any longstanding illnesses or disabilities

Retention

Nineteen participants (45%) withdrew from the study: 12 (28%) between T0 and T1; and seven (17%) between T2 and T3 (Figure 1). Although in general reasons for withdrawal were not provided, two patients were too unwell and two participants died during the study. The only factor associated with withdrawal was higher baseline anxiety (M= 6.4, SD = 8.1) compared to those who completed the study (M= 4.2, SD = 3.8) (t (40) = 1.16, p = 0.001).

Acceptability of outcome measures

In interviews, participants reported taking 10-40 minutes to complete outcome measures. All were judged appropriate except the Scottish Physical Activity Questionnaire (SPAQ). Eight participants reported it was repetitive and difficult to complete as illustrated below:

> *The SPAQ section… a lot of licking my fingers and sticking it in the air, lots of 'think of a number' type thing, it was hard to think. A pre-warning of what was going to be required might have been helpful so you could fill this section in accurately. (3013, male, prostate cancer)*

These problems were reflected in data quality, with 45% completing the daily activity data incorrectly or not at all. Further, insufficient numbers of participants returned the pedometer data at all assessments to permit analysis.

Assessment of methodological components of the trial

Application of the ADePT framework[18] suggests most components of the trial protocol worked well (Appendix 1). The only exception was participants were not recruited from three tumour groups: head and neck, colorectal and skin.

Safety and engagement with the intervention

No adverse outcomes or events were reported. Views about CanWalk were positive from the ESQ and interviews, although interview data suggested engagement with, and

adherence to, WfH group walks varied. Most (4/5) interviewees from the intervention group participated in WfH group walks plus self-initiated walks. One completed self-initiated walks only.

Hawthorne Effect

During interview, only one participant in the control group reported receiving information about exercise over the course of the study. Yet on the ESQ, 9 out of 12 said taking part in this study had stimulated them to undertake more physical activity. Interview findings confirmed this effect in three of the five control group members:

> *I found it all quite motivating as after filling in the questionnaire and using the pedometer I found that I was more focused on walking. I even did a long walk with the Ramblers which I haven't done in a while. It prompted me to be more fit. I sit less on the sofa now and try to get myself outside. (5020, female, haematological cancer with pedometer)*

Participants' views on the intervention

At 24-weeks, nine participants completed the ESQ and results indicated that most (n=8) found it useful and were satisfied (n=7). Nevertheless, a number of barriers to the intervention were identified at interview. Some participants preferred self-initiated walking, and felt WfH groups, while beneficial for some, did not suit everybody. Reasons included dislike of group activities and accessibility issues. One younger participant who withdrew from the study felt the group walks were more appropriate for

older people and decided to continue with self-initiated walks only. Consequently, some interviewees suggested modifying the intervention to offer alternative options to the group walks.

Between group outcomes

Primary RCT outcome: Quality of life

Whilst at baseline the control group reported lower median FACT-G (Functional Assessment of Cancer Therapy- General) QoL scores than the intervention (53 vs 58, respectively), scores were comparable during follow-up (Table 2). Likewise the FACT-G sub-scales scores at T1-T3 were relatively high and stable for both intervention and control groups (Table 2).

Table 2
Primary outcome measure for possible RCT by assessment time and study group

Quality of life	Study group	Baseline Mean (SD) *Median (IQR)*	6 week Mean (SD) *Median (IQR)*	12 week Mean (SD) *Median (IQR)*	24 week Mean (SD) *Median (IQR)*
FACT-G[a] Total score[19]	**Control**	52 (9.1) *53 (11.0)*	51 (11.2) *56(17.5)*	50 (7.9) *52 (13.0)*	48 (12.7) *54 (20.0)*
	Intervention	57 (5.2) *58 (4.0)*	56(6.3) *57 (7.25)*	55 (5.5) *56 (4.0)*	57 (6.9) *56 (10.5)*
Cohen's d effect size (95% CI)		0.67 (0.04,1.28)	0.55 (-0.19, 1.26)	0.73 (-0.07, 1.49)	0.79 (-0.09, 1.62)
Physical well-being sub-scale	**Control**	22(5.8) *24(7.0)*	21 (5.7) 21 (10.5)	22 (5.7) *25 (11.0)*	23 (4.5) *24 (7.5)*
	Intervention	23(4.7) *26 (6.0)*	25(2.4) 26 (4)	25 (3.3) *26 (6.0)*	23 (4.7) *25 (4.7)*

Table 2

Primary outcome measure for possible RCT by assessment time and study group

Quality of life	Study group	Baseline Mean (SD) *Median (IQR)*	6 week Mean (SD) *Median (IQR)*	12 week Mean (SD) *Median (IQR)*	24 week Mean (SD) *Median (IQR)*
Cohen's d effect size (95% CI)		0.19 (-0.42, 0.79)	0.91 (0.14, 1.64)	0.64 (-0.15, 1.39)	0.00 (-0.82, 0.82)
Social and family well-being sub-scale	**Control**	20 (6.1) *21 (11)*	19 (7.0) 21(10.75)	19 (6.2) *19 (10.0)*	18 (7.3) *20 (12.5)*
	Intervention	22(3.6) *23 (6.0)*	22 (3.9) *23 (6.0)*	22 (4.0) *23 (4.0)*	22 (5.5) *23 (8.0)*
Cohen's d effect size (95% CI)		0.40 (-0.22, 1.00)	0.53 (-0.21, 1.24)	0.57 (-0.22, 1.32)	0.61 (-0.26, 1.43)
Emotional well-being sub-scale	**Control**	17 (5.2) *16 (8.0)*	18 (4.4) *19 (5.3)*	19 (3.8) *19 (6.0)*	20 (3.3) *20 (6.5)*
	Intervention	17 (5.5) *19 (7.0)*	20 (3.6) *20 (4.0)*	20 (3.7) *21 (6.0)*	18 (3.8) *18 (6.2)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	0.50 (-0.24, 1.21)	0.27 (-0.50, 1.02)	-0.57 (-1.39, 0.29)
Functional well-being sub-scale	**Control**	18(5.0) *19 (9.0)*	17 (6.6) *17.5 (10.3)*	19 (6.5) *19 (11.0)*	21 (7.6) *23 (14.5)*
	Intervention	21(6.5) *23 (13.0)*	23(5.6) *26 (8.0)*	23 (4.7) *23 (7.0)*	23 (5.3) *25 (8.0)*
Cohen's d effect size (95% CI)		0.52 (-0.11, 1.12)	0.98 (0.20, 1.71)	0.70 (-0.10, 1.46)	0.30 (-0.54, 1.12)

[a] FACT, Functional Assessment of Cancer Therapy- General

Secondary RCT outcomes

Comparable results for both groups were also found for the secondary outcomes with median scores remaining relatively stable across assessments. Detailed descriptive analysis of subscale scores provide evidence of some floor or ceiling effects (data not shown). For instance, the EQ-5D (health status) showed a clear floor effect with most participants reporting few symptoms at each time point.

The GPPAQ physical activity index (PAI), which includes activity at work, physical exercise and cycling (but not walking), indicated the intervention group was more active at all assessments than the control, and physical activity levels for both groups declined over the study period. However, the GPPAQ item which measures walking activity indicated that the proportion of participants doing at least 3-hours of walking a week increased in both groups (Table 3).

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
Global fatigue score[20]	**Control**	36(21.6) *31 (28.0)*	35 (22.0) *43 (37.0)*	32 (21.9) *26 (40.0)*	28 (24.5) *18 (47.5)*
	Intervention	32 (22.3) *33(43.0)*	18 (15.9) *15 (24.0)*	23 (17.3) *25 (33.0)*	29 (19.1) *31 (24.7)*
Cohen's d effect size (95% CI)		-0.18 (-0.78, 0.43)	-0.89 (-1.61, -0.11)	-0.45 (-1.20, 0.32)	0.04 (-0.78, 0.87)
Exercise self-efficacy[21]	**Control**	28 (6.0) *29(9.0)*	29 (5.5) *29 (6.0)*	29 (4.6) *30 (6.0)*	29 (5.0) *28 (4.5)*
	Intervention	30 (6.0) *31 (8.0)*	33 (5.2) *33 (10.0)*	33 (5.4) *36 (10.0)*	34 (4.6) *34 (8.25)*
Cohen's d effect size (95% CI)		0.33 (-0.28, 0.94)	0.75 (-0.01, 1.71)	0.80 (-0.01, 1.56)	1.01 (0.10, 1.84)
Stress total score[22]	**Control**	9(9.0) *6(12.0)*	8 (9.1) *5 (9.5)*	4 (4.7) *4 (8.0)*	9 (9.5) *8 (0-26)*
	Intervention	8(9.7) *2 (18.0)*	4 (5.1) *4 (6.0)*	5 (5.9) *4 (10.0)*	3 (3.6) *2 (6.0)*
Cohen's d effect size		-0.11	-0.54	0.19	-0.76

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
(95% CI)		(-0.71, 0.50)	(-1.26, 0.20)	(-0.57, 0.94)	(-1.59, 0.11)
Anxiety total score[22]	**Control**	6(5.3) *6(6.0)*	5 (5.4) *4 (6.5)*	3 (3.1) *2 (6.0)*	6 (8.3) *2 (9.0)*
	Intervention	4 (7.1) *2 (4.0)*	2 (3.3) *0 (2.0)**	4 (6.0) *2 (4.0)*	2 (2.7) *0 (5.0)*
Cohen's d effect size (95% CI)		-0.32 (-0.92, 0.30)	-0.67 (-1.39, 0.08)	0.21 (-0.55, 0.96)	-0.60 (-1.42, 0.26)
Depression total score[22]	**Control**	8(7.2) *6 (11.0)*	8 (8.4) *2 (14.0)*	5 (6.5) *2 (9.0)*	8 (9.0) *2 (13.0)*
	Intervention	8(10.1) *6 (15.0)*	3 (4.9) *0 (4.0)**	4 (5.9) *0 (6.0)*	4 (5.7) *2 (9.0)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	-0.73 (-1.43, 0.03)	-0.16 (-0.91, 0.60)	-0.52 (-1.33, 0.34)
EQ-5D score[23]	**Control**	2 (0.66) *2 (1.0)*	2 (0.5) *2 (1.0)*	2 (0.6) *1 (1.0)*	1 (0.5) *1 (0.7)*
	Intervention	1 (0.52) *1 (1.0)*	1 (0.4) *1 (0.8)*	1 (0.4) *1 (1.0)*	1 (0.4) *1 (0.6)*
Cohen's d effect size (95% CI)		-1.68 (-2.35, -0.95)	-2.21 (-3.05, -1.25)	-1.95 (-2.80, -0.98)	0.00 (-0.82, 0.82)
EQ-VAS Your health today score out of 100[23]	**Control**	72 (22.6) *80 (40)*	82 (12.1) *78 (20.3)*	76 (26.4) *90 (41.5)*	79 (19.6) *80 (31.0)*
	Intervention	75 (17.0) *70 (30)*	84 (12.8) *85 (20.0)*	78 (18.1) *80 (28.8)*	81 (14.9) *80 (25.0)*
Cohen's d effect size (95% CI)		0.15 (-0.46, 0.75)	0.16 (-0.56, 0.87)	0.09 (-0.67, 0.84)	0.17 (-0.67, 0.99)
Active/ moderately active[24]		**N (%)**	**N (%)**	**N (%)**	**N (%)**
	Control	2 (10)	0	1(7)	0
	Intervention	6(29)	5 (34)	4 (31)	2(20)
Walked 3 ≥ hours in last 7days[24]	**Control**	9 (47)	7 (54)	11 (79)	9 (82)
	Intervention	9 (43)	9 (70)	7 (58)	5 (62)

In contrast, interview data showed that the intervention group felt that they benefited in terms of physical, emotional and psychological, social wellbeing and lifestyle changes

(see Table 4 for illustrative quotes). Most participants reported being previously active and understood the benefits of being more physically active. On the ESQ, 7 out of 10 of the intervention group reported they had set physical activity goals at baseline which they achieved by 24-weeks. In interviews, all participants in the intervention group and 3 out of 5 in the control group reported being more active by 24-weeks.

Wellbeing and lifestyle benefits, such as weight loss, also motivated participants to increase the amount they walked. They spoke about how it improved their overall quality of life and helped them maintain a positive attitude towards their illness. Many participants in the intervention group spoke of the social benefits of participating in the WfH groups (Table 4 for illustrative quotes).

Table 4 Participants views and experiences of the intervention

Theme	Illustrative comments
Physical benefits	*Its praises should be sung more widely, it really would deserve that. It had a revolutionary effect on me. I'm a walking bore now I'm afraid! It was just the right thing at just the right time for me. I think more about walking now, I think can I walk there instead of catching the bus. It's a fairly painless way of keeping weight down while still eating a little bit of what you enjoy….* (3022 male, prostate cancer no pedometer) *I have walked ever since at least 3 days a week. This study has stimulated me. I drop my daughter off at school then go with the dog for a long walk. I have noticed the difference physically. I am back on chemo now and have noticed differences with side effects compared to last year. Last year I had oedema which I don't this time and I just feel a lot fitter this time round. In general, I have a little more stamina than before.* (5016, male, haematological cancer, with pedometer)
Emotional/ Psychological wellbeing	*I would definitely recommend it, particularly to people who are not actively sporty or for sedentary people. Being diagnosed with cancer is a pretty devastating thing and being told its terminal is even more devastating and when I'm on the walks I forget about the cancer, they have helped me enormously by keeping me physically fit and keeping me well but also mentally. I bang on a lot less to those around me about dying than I used to. And that's got to be good for them as well.* (3022, male prostate cancer)

Table 4 Participants views and experiences of the intervention	
Theme	Illustrative comments
Social benefits	*I have been doing Nordic walking [WfH] at least once a week - it has made a huge difference to me physically and mentally. It makes me do more than I would if I was walking on my own, I have met all sorts of people and as I live on my own it's great being out and meeting other people.* (4065, female gynaecological cancer with pedometer)
Wellbeing and lifestyle benefits	*The impact has been immense! Gave me the motivation to not only increase walking activity from minute to 3-4 hours per week but also to reduce weight to desired 77-80kg by altering diet/ reducing sweets/sugars. Great boost to morale-no longer dwell on being terminal - just on getting on with making life as enjoyable as possible, greatly helped by friends made on regular 'walks for life'.* (3022, male, prostate cancer)
Barriers to group walks	*There was only one walk I could find locally that lasted more than 30 mins and seemed to cover a reasonable distance. I turned up to meet and they were meeting in the tea room. I know this sounds a bit ridiculous but I wanted to see who was in the group rather than going straight in. It seemed that everyone in the group was quite a bit older than me, and they spent the first 20mins of the walking time drinking tea in the cafe. When they moved off they were walking quite slowly. I'm not criticising the validity of these social group walks but I was looking for something a bit more energetic, and with people closer in age to me* (8003, male, colorectal cancer).

DISCUSSION

This study aimed to assess the feasibility and acceptability of a RCT of a community-based walking programme in people with recurrent/metastatic cancer. Our results indicate that most self-initiated walks were acceptable, though some reported being unable to commit to the WfH groups regularly, largely due to work commitments. The CanWalk intervention, based on the UK's NICE (National Institute for Healthcare and Clinical Excellence) guidance for promoting physical activity,[25,26] includes active components identified as helping individuals change their behaviour,[27] such as goal setting, planning and social support. However, it is possible that including more monitoring and tailored feedback could be beneficial and could be offered remotely

through the use of apps and/or websites. This is supported by comments from participants from both the intervention and support groups indicating they found completing the outcome measures stimulated them to increase their physical activity levels.

Key elements of feasibility testing have been identified by Bowen et al (2009)[28] and are used (highlighted in bold) here to evaluate whether the CanWalk intervention warrants further investigation. A central focus to our study involved estimating **demand** for the intervention. Forty per cent of those eligible to participate in the study consented. This is comparable to recruitment rates reported in similar studies, [29,30] and not unexpected in a population comprising people with advanced cancer. Almost a third withdrew within 6-weeks, which is higher than found in previous research, however these studies those with early stage cancer [31] or had shorter follow-ups (4-weeks).[29,30] Our preliminary evidence indicated an association between withdrawal and higher baseline anxiety. This warrants further exploration and consideration of ways the intervention could be made more appealing and acceptable for people with symptoms of anxiety, perhaps through a buddy system or by enhancing the motivational interview component with 'booster' follow-up sessions.

This feasibility study also explored the **implementation** of the study and intervention. Importantly, based on the study data, a power calculation was performed for target recruitment for a future trial. However, the proposed recruitment estimate was not

feasible within the timeframe; despite extending recruitment and widening the eligibility criteria to include other diagnoses.

For clinicians to change their practice, they require evidence of the **practicality** of the interventions ie that they can be delivered within existing means and resources.[28] The complementary components of the intervention promoted physical activity. The researchers spent approximately 20-minutes per person delivering CanWalk. This suggests that if the intervention proves effective, it is could be sufficiently brief for delivery by health care professionals in the clinical setting.

Limited-efficacy testing gives an indication of the likely impact of the intervention, although not the primary aim of a feasibility study. Results suggest few differences between groups across the outcome measures at any time point. Arguably, this inability to detect change could be attributed to the small sample size, as the pilot study was insufficiently powered to detect subtle differences. Further, similar to other studies[29,30,32] contamination may have occurred whilst assessing activity levels using outcome measures which reportedly stimulated *all* participants to engage in physical activity. Likewise, participants highlighted that using pedometers with both groups had a similar effect. This suggests an alternative method of assessing walking behaviour is required.

Detailed descriptive evaluation of the performance of the outcome measures suggests that whilst being reliable, some of the measures may not be sensitive to change as they demonstrated floor/ceiling effects. Moreover, feedback from the ESQ and interviews

suggested social support was a key perceived benefit of participating in the WfH walks, but this was not reflected in the FACT-G social wellbeing sub-scale scores. However, this may be because it focuses entirely on support from family and relatives and so would not be sensitive to benefits from making wider social contacts. It will therefore be important to include a brief social support and engagement measure (such as the Duke-Social Support Questionnaire) [33] in future research. Our findings demonstrate the importance of pilot testing questionnaires. As many participants reported the SPAQ was time consuming and confusing suggesting a need to use other measures of physical activity for both measuring adherence to the intervention and outcomes. Pedometer data were often not returned thus alternative methods for measuring the intensity, duration and frequency of physical activity in any future study are recommended. Whilst accelerometers have been used in previous studies they often require expert knowledge to interpret and analyse results, so the use of off-the-shelf wearable technologies may offer an alternative and more cost-effective approach. [34]

Some participants were, from the outset, already active which contributed to difficulty in detecting between group changes. Thus it may be preferable to only recruit people who are judged to be inactive. However, this will reduce the number eligible to participate and exclude people who, although active, wish to increase the amount they walk.

Based on the study findings a number of **adaptations** are proposed for a future study including the refinement of the study samples to include different comparison groups, for example, a tailored CanWalk intervention and written information only group.

Furthermore, it will be important to ensure outcome measures used match the benefits reported by participants in the interviews, such as feeling fitter and having more stamina (e.g. functional walking/fitness tests such as incremental shuttle walk or 6-minute walk test; being less inactive (e.g. measure of sedentary behaviour), weight loss (e.g. weight, body mass index, hip to waist ratio) and symptom control.

Several limitations were identified in the study. The recruitment centres were London-based thus limiting generalisability. Although we were able to collect reasons for non-participation, unfortunately we were not able to collect data on the demographic or clinical characteristics of those who declined participation. Further, the qualitative sample was small, limiting the extent of in-depth analysis of participants' perceptions and experiences. Another limitation is that the views of participants from Black and minority ethnic groups are underrepresented as the study recruited primarily Caucasian participants and English speakers.

Conclusions

This study investigated the feasibility and acceptability of undertaking a RCT of a community-based walking programme to enhance QoL in people with recurrent or metastatic cancer. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. However, further exploration of the intervention is required to refine and understand its components and enhance its capacity to create measurable change.

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Contributorship statement: VT and JH recruit participants and were responsible for day-to-day study coordination, delivery of the intervention and drafted the manuscript. JA is the study chief investigator and provided the concept, hypotheses, study design and methods, recruitment of participants, is responsible for the overall study management and drafted and critically revised the manuscript. ER, MVH, AP, LM, JG and JF participated in the design of the study, critically revised the protocol and the manuscript. All authors read and approved the final manuscript.

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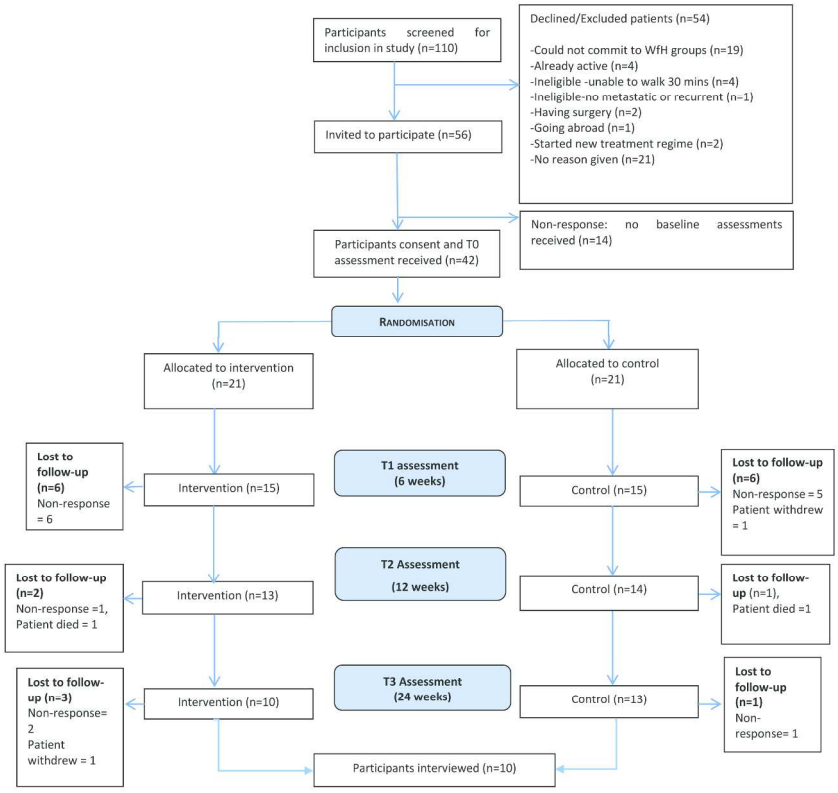

Figure 1. Flow of participants through the study

210x297mm (300 x 300 DPI)

Online supplementary information

Appendix 1
Summary of findings using ADePT methodological issues for feasibility research

Methodological issues	Findings	Evidence
1. Did the feasibility study allow a sample size calculation for the main trial?	Achieved	42 of the target of 60 participants achieved in feasibility study. 108 participants would need to be randomised to each group for the main trial.
2. What factors influenced eligibility and what proportion of those approached were eligible?	Mainly due to refusal to participate	Reasons provided included being: -unable to commit to WfH groups (n=19) -physically active already (n=4) -Ineligible -unable to walk 30 mins (n=4) -Ineligible-no metastatic or recurrent (n=1) -Having surgery (n=2) -Going abroad (n=1) -Started new treatment regime (n=2)
3. Was recruitment successful?	Recruitment was fairly successful.	42/105 screened participants. This is reasonable for a physical activity feasibility study including people with recurrent and metastatic cancers.
4. Did eligible participants consent?	Consent of eligible participants was good.	42/56 patients who were provided with the baseline questionnaire and consent returned these.
5. Were participants successfully randomized and did randomization yield equality in groups?	Randomization procedures worked well and equality in groups for age and sex were achieved. However, the control group were far more active at baseline suggesting the minimisation criteria of walking 3 hours each week was not sensitive enough (because some participants engaged in other physical activity).	21 men and 21 women with comparable distribution between control and intervention. Mean and median age in both groups was comparable and representative of the target population. Equal numbers of participants in each group walked for at least 3 hours, however 6 of the control group were classed as 'active' compared with 2 in the intervention group.
6. Were the blinding procedures adequate?	Not applicable.	

Appendix 1 Summary of findings using ADePT methodological issues for feasibility research		
7. Did participants adhere to the intervention?	Adherence for those who were randomised to the intervention was good; however, some participants adapted the intervention.	Questionnaires and interviews. Participants took part in the walking groups during the 12 week period. Some continued with these groups and others continued to walk on their own or with friends/family
8. Was the intervention acceptable to the participants?	The intervention was mostly acceptable.	Questionnaires and interviews. Overall participants enjoyed taking part. One younger participant withdrew because he did not think the walking groups were age appropriate.
9. Was it possible to calculate intervention costs and duration?	Partially achieved.	The MI intervention lasted 10-15 minutes. Full costs should be included in future RCT.
10. Were outcome assessments completed?	Completion of outcome assessment was good between baseline and 12 weeks (intervention period). Attrition was more evident at 24 weeks.	Baseline: 42 questionnaires/ 14 pedometer logs completed 6 weeks: 30 questionnaires/ 11 pedometer logs completed 12 weeks: 27 questionnaires/ 9 pedometer logs completed 24 weeks: 23 questionnaires/ 8 pedometer logs completed
11. Were outcomes measured those that were the most appropriate?	Partially.	Although good internal reliability was indicated (Cronbach α >0.80) there was evidence of ceiling/floor effects. SPAQ was found to be unacceptable to participants with inadequate data quality.
12. Was retention to the study good?	After an initial withdrawal after randomisation 6 to 12 week retention was good. Retention was reasonable at 24 weeks for a physical activity feasibility study including people with recurrent and metastatic cancers.	See outcome assessment above (10).
13. Were the logistics of running a multicentre trial assessed?	Some clinics were better at recruiting than others but both hospital sites recruited.	Feedback from site staff suggests that dedicated research nurses or researchers based at each hospital are recommended for the main RCT. Recruitment was easier when researchers attended all relevant clinics.

Appendix 1 Summary of findings using ADePT methodological issues for feasibility research		
14. Did all components of the protocol work together?	All components of the protocol worked well.	No difficulties identified in processes or implementation by the researchers or site staff (research nurses/clinicians).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Completed for CANWALK: A RANDOMISED FEASIBILITY TRIAL OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER.

Please note the feasibility/pilot RCT COSORT statement is not yet available and so we have completed the standard CONSORT checklist.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1, feasibility randomised trial
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	7 (note feasibility RCT)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7-8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	n/a
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8, 11
	13b	For each group, losses and exclusions after randomisation, together with reasons	8, 11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7, 8
	14b	Why the trial ended or was stopped	n/a (feasibility trial)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8,12
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-15, 19-21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21- 24, 25

Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

CANWALK: A FEASIBILITY STUDY WITH EMBEDDED RANDOMISED CONTROLLED TRIAL PILOT OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER

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CANWALK: A FEASIBILITY STUDY WITH EMBEDDED RANDOMISED CONTROLLED TRIAL PILOT OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER

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ABSTRACT

Objectives: Walking is an adaptable, inexpensive and accessible form of physical activity. However its impact on quality of life and symptom severity in people with advanced cancer is unknown. This study aimed to assess the feasibility and acceptability of a randomised controlled trial (RCT) of a community-based walking intervention to enhance quality of life (QoL) in people with recurrent/metastatic cancer.

Design: We used a mixed-methods design comprising a two-centre RCT and nested qualitative interviews.

Participants: Patients with advanced breast, prostate, gynaecological or haematological cancers randomised 1:1 between intervention and usual care.

Intervention: The intervention comprised Macmillan's 'Move More' information, a short motivational interview with a recommendation to walk for at least 30 minutes on alternate days and attend a volunteer-led group walk weekly.

Outcomes: we assessed feasibility and acceptability of the intervention and RCT by evaluating study processes (rates of recruitment, consent, retention, adherence and adverse events), and using end of study questionnaires and qualitative interviews. Patient reported outcome measures (PROMS) assessing quality of life (QoL), activity, fatigue, mood and self-efficacy were completed at baseline and 6, 12 and 24 weeks.

Results: We recruited 42 (38%) of eligible participants. Recruitment was lower than anticipated (goal n=60), the most commonly reported reason being unable to commit to walking groups (n=19). Randomisation procedures worked well with groups evenly matched for age, sex and activity. By week 24, there was a 45% attrition rate. Most

PROMs whilst acceptable were not sensitive to change and did not capture key benefits.

Conclusions: The intervention was acceptable, well tolerated and the study design was judged acceptable and feasible. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. Consequently, an effectiveness RCT is warranted, with some modifications to the intervention to include greater tailoring and more appropriate PROMs selected.

(297 words)

Trial registration

ISRCTN42072606

Strengths and limitations of this study

- The study assessed the feasibility and acceptability of a randomised control trial (RCT) of community-based walking for people with recurrent or metastatic breast, gynecological, haematological or prostate cancers.
- The intervention made use of freely-available walking groups and information, combined with a brief motivational interview and recommendation to walk for at least 30 minutes on alternate days and attend a weekly walking group.
- A mixed-methods design, including a two-centre RCT with nested qualitative interviews, was used to assess feasibility and acceptability of the intervention *and* RCT, and test the utility of different patient report outcome measures (PROMS).
- The recruitment centres were London-based limiting generalisability.

- Views of participants from Black and ethnic minority patients were underrepresented as the majority of participants were Caucasian and English speaking.

INTRODUCTION

Life expectancy of people with recurrent or metastatic cancer is increasing but this patient group is at considerable risk of experiencing psychological [1] and physical health problems.[2,3] Despite growing evidence of significant health benefits, physical activity declines considerably during cancer treatment and remains low afterwards.[4] There is some evidence that maintaining or increasing physical activity in cancer patients can enhance QOL and well-being as disease progresses.[5,6] However, activity-based interventions are typically supervised and require attendance at specialist facilities, potentially limiting acceptability and economic sustainability. [5,7]

Brisk walking is an adaptable, inexpensive and effective physical activity [8,9] that has been shown to improve QoL, physical functioning and fatigue.[5,7] It can be undertaken alone or in groups and is not restricted to specific facilities or settings – a factor associated with longer-term behaviour change.[10] However, it is unclear whether walking is acceptable to, or improves physical and psychological wellbeing of, people with recurrent or metastatic cancer. We therefore assessed the feasibility and acceptability of a community-based walking for people with recurrent or metastatic cancer and randomised controlled trial (RCT). Detailed methods have been published elsewhere.[11] This article reports on: acceptability and feasibility of the study design and intervention, and provides preliminary evidence of efficacy.

MATERIALS AND METHODS

Study design and participants

Feasibility of using RCT methodology to test the effectiveness of the walking intervention was assessed using a sequential, explanatory mixed-methods design[12] with nested qualitative interviews. The study was undertaken between April and November 2014 in two London NHS Foundation Trusts.

We aimed to recruit at least 60 patients, in order to be able to estimate the standard deviation of the QoL outcome and estimation of the true treatment difference and perform a power calculation and sample size for the any future RCT [11] as recommended for feasibility trials.[13,14] Eligible participants were: i) ≥ 16 years; ii) diagnosed with recurrent (advancing) or metastatic breast, colorectal, upper gastrointestinal, gynaecological, haematological, head and neck, melanoma or prostate cancer (specific diagnosis inclusion/exclusion criteria published elsewhere[11]).

Recruitment and randomisation

Initially, healthcare professionals (HCP) approached potential participants; however, because HCP were mostly too busy to identify patients, recruitment was lower than expected; therefore, research staff were assigned to recruit. Participants completed postal questionnaires at baseline (T0), 6 (T1), 12 (T2) and 24 (T3) weeks following recruitment (see Figure 1). Additionally, those in the intervention group were asked to record their Walking for Health participation- including date and location of walks attended- on a simple form.

Consenting participants completed baseline questionnaires before randomisation. They were allocated, via an online automated system, to either the control (standard care) or intervention group using minimisation on the basis of age (≤65, ≥66 years), sex (male, female) and baseline activity level (<1 hour /week, ≥1 hour/week).

Physical activity intervention

The 12-week *CanWalk* intervention aimed to motivate participants to walk for *at least* 30 minutes on alternate days. This target was selected as an acceptable minimum for those who may be sedentary and/or have reduced physical functioning. A 15-minute motivational telephone (MI) interview, based on the UK's National Institute for Health and Clinical Excellence (NICE) guidance on promoting physical activity in primary care [15,16] was provided (by authors VT or JH). Participants were additionally provided with printed material promoting activity, (Macmillan Cancer Support (MCS) 'Move More' booklet) [17] and encouraged to attend a weekly group walk of their choice from the *Walking for Health* (WfH) programme. WfH is a UK-wide network of free walking groups funded by Macmillan Cancer Support and hosted by The Ramblers, suitable for people living with long-term condition.[18] MI is a patient-centred counselling style that enhances an individual's motivation to change. The MI trained researchers, assessed the patient's readiness to change and motivation to adhere to the intervention, and used MI techniques to stimulate their use of study materials and make progress towards their own walking goals.[19] Researchers encouraged participants to plan how they could incorporate the weekly WfH groups alongside walking independently or with family/friends. Interviews were audio recorded with permission and an expert in

motivational interviewing provided supervision to the researchers to ensure adherence to operational procedures and the principles of motivational interviewing.[11] The control group were asked to continue with their usual activities.

Primary outcomes: Feasibility measures

Data were collected on rates of recruitment, consent, retention and adverse events. Reasons for non-participation and withdrawal were collected, where possible. Participants completed an end of study questionnaire (ESQ) assessing acceptability of CanWalk, randomisation process, study methods and outcome measures. Adherence to CanWalk was evaluated over 7-days at each assessment using a self-report measure. We assessed the feasibility of capturing objective data on walking behaviour by randomly allocating 50% of the control and intervention groups to use a pedometer (Omron HJ-321-E). Participants were asked to wear them for seven consecutive days at each time-point and complete a usage log recording their daily step count. Additionally, the intervention group was asked to keep a log of WfH walks they undertook. Where possible, reasons for withdrawal from the study were collected.

Ten participants (5 per group; 6 men and 4 women; 5 >65 years; 9 White British or Irish) took part in semi-structured telephone interviews exploring the acceptability of CanWalk, randomisation process and outcome measures.

Secondary outcomes: Between group outcomes

Outcome measures for assessing efficacy of the intervention included quality of life (the primary RCT outcome measure), physical activity, mood, exercise self-efficacy, fatigue and performance status (the secondary RCT outcome measures).[11]

Data analysis

We examined differences between the baseline characteristics of those who completed or withdrew from the study using chi-square and *t*-tests, as appropriate. Descriptive statistics for all between group outcome measures are presented including means (SD), medians (interquartile range) and frequencies. Cohen's d with 95% confidence intervals (95% CI) was calculated for effect size. The mean (SD) for the main outcome (QoL) was used to estimate sample size for the effectiveness trial. All data were analysed using SPSS (v21) or SAS (v9.4).

Audio recordings of qualitative interviews were transcribed verbatim and analysed using the framework approach.[20] Descriptive analysis was undertaken of the ESQ and free-text comments integrated with the qualitative data. Findings from the qualitative and quantitative analyses are presented concurrently. The study design is reviewed using the ADePT framework(a process for decision-making after pilot and feasibility trials) [21] (Appendix 1).

Ethical Approval

Ethical approval was gained from the National Research Ethics Service (Ref: 13/NW/0860) and research governance approval granted by both NHS Trusts.

RESULTS

Feasibility assessment

Recruitment

One hundred and ten people were eligible to participate; 49 (47%) declined - primarily because of work commitments. Although willing to walk on alternate days, they could not commit to a weekly walking group. Whilst initial interest in participating was relatively high (53%), the recruitment rate was lower (40%). Reasons for this are unknown. In interviews, participants reported the randomisation process was acceptable with 21 allocated to each group. Whilst there was little difference in most of the demographic and clinical characteristics between the groups (Table 1), almost half of the sample was educated to at least degree level - higher than would be expected in the general population.

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Men			
Mean age (SD)	66.2 (10.2)	65 (11.7)	65.6 (10.8)
Median age (range)	*68 (50-79)*	*71 (40-80)*	*69 (40-80)*
N	*10 (48)*	*11(52)*	*21*
Women			
Mean age (SD)	58 (11.6)	60 (12.2)	59(11.6)
Median age (range)	*59 (35-79)*	*59 (38-78)*	*59 (35-79)*
N	*11(52)*	*10(48)*	*21*

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
Ethnic origin	**N (%)**	**N (%)**	**N (%)**
White	17 (81)	17 (81)	34 (81)
Black	4 (19)	1 (5)	5 (12)
Other ethnic groups	0	2 (9)	2 (4)
Marital status			
Married	12 (57)	16 (80)	28 (68)
Widowed	0 (0)	1 (5)	1 (2)
Divorced/separated	4 (19)	1 (5)	5 (12)
Single	5 (24)	2 (10)	7 (17)
Employment status Employed (full or part-time)	4 (20)	6 (29)	10 (24)
Sick leave	3 (15)	2 (10)	5 (22)
Retired	10 (50)	10 (48)	20 (49)
Unemployed	2 (10)	3 (14)	5 (12)
Disabled and unable to work	1 (5)	0 (0)	1 (2)
Highest educational attainment GCSE/O Levels or equivalent	4 (20)	5 (25)	9 (23)
A Levels or equivalent	1 (5)	5 (25)	6 (15)
Degree/higher degree	12 (60)	7 (35)	19 (48)
No formal qualifications	3 (15)	3 (15)	6 (15)
Owner-occupier of housing	18 (86)	17 (81)	35 (83)
Has any caring responsibilities	3 (15)	1 (5)	4 (10)
Primary cancer			
Breast	4 (19)	3 (14)	7 (17)
Colorectal	0 (0)	5 (1)	1 (2)
Gynaecological	4 (19)	5 (24)	9 (21)
Haematological	4 (19)	5 (24)	9 (21)
Prostate	8 (38)	7 (33)	15 (36)
Upper GI	1 (5)	0 (0)	1 (2)
Number of years since diagnosis Less than 1 year	6 (29)	4 (21)	10 (25)
1-2 years	8 (38)	6 (32)	14 (35)
3-4 year	2 (10)	2 (10)	4 (10)
5-9 year	4 (20)	4 (21)	8 (20)
10 years or more	1 (5)	3 (16)	4 (10)
Previous treatments for cancer[1] Surgery	8 (38)	8 (42)	16 (40)
Radiotherapy	8 (40)	10 (53)	18 (46)
Chemotherapy	14 (67)	11 (55)	25 (61)
Other	10 (59)	10 (53)	25 (61)

Table 1
Demographic and clinical characteristics of the CanWalk intervention, by study group

Demographic or clinical characteristics	Control (N=21)	Intervention (N=21)	All
On-going cancer treatment[2]	16 (76)	17 (81)	33 (79)
Any longstanding illness or disability[3]	9 (50)	4 (20)	13 (31)
Main hospital Site 1 Site 2	 15 6	 15 6	 30 (71) 12 (29)

[1] Self-reported treatments, categories are not mutually exclusive

[2] Self-reported whether receiving on-going cancer treatment

[3] Self-reported whether any longstanding illnesses or disabilities

Retention

Nineteen participants (45%) withdrew from the study: 12 (28%) between T0 and T1; and seven (17%) between T2 and T3 (Figure 1). Although in general reasons for withdrawal were not provided, two patients were too unwell and two participants died during the study. The only factor associated with withdrawal was higher baseline anxiety (M= 6.4, SD = 8.1) compared to those who completed the study (M= 4.2, SD = 3.8) (t (40) = 1.16, p = 0.001).

Acceptability of outcome measures

In interviews, participants reported taking 10-40 minutes to complete outcome measures. All were judged appropriate except the Scottish Physical Activity Questionnaire (SPAQ). Eight participants reported it was repetitive and difficult to complete as illustrated below:

> *The SPAQ section… a lot of licking my fingers and sticking it in the air, lots of 'think of a number' type thing, it was hard to think. A pre-warning of what was*

going to be required might have been helpful so you could fill this section in accurately. (3013, male, prostate cancer)

These problems were reflected in data quality, with 45% completing the daily activity data incorrectly or not at all. Further, insufficient numbers of participants returned the pedometer data at all assessments to permit analysis.

Assessment of methodological components of the trial

Application of the ADePT framework[18] suggests most components of the trial protocol worked well (Appendix 1). The only exception was participants were not recruited from three tumour groups: head and neck, colorectal and skin.

Safety and engagement with the intervention

No adverse outcomes or events were reported. Views about CanWalk were positive from the ESQ and interviews, although interview data suggested engagement with, and adherence to, WfH group walks varied. Most (4/5) interviewees from the intervention group participated in WfH group walks plus self-initiated walks. One completed self-initiated walks only.

Hawthorne Effect

During interview, only one participant in the control group reported receiving information about exercise over the course of the study. Yet on the ESQ, 9 out of 12 said taking part in this study had stimulated them to undertake more physical activity. Interview findings confirmed this effect in three of the five control group members:

> *I found it all quite motivating as after filling in the questionnaire and using the pedometer I found that I was more focused on walking. I even did a long walk with the Ramblers which I haven't done in a while. It prompted me to be more fit. I sit less on the sofa now and try to get myself outside. (5020, female, haematological cancer with pedometer)*

Participants' views on the intervention

At 24-weeks, nine participants completed the ESQ and results indicated that most (n=8) found it useful and were satisfied (n=7). Nevertheless, a number of barriers to the intervention were identified at interview. Some participants preferred self-initiated walking, and felt WfH groups, while beneficial for some, did not suit everybody. Reasons included dislike of group activities and accessibility issues. One younger participant who withdrew from the study felt the group walks were more appropriate for older people and decided to continue with self-initiated walks only. Consequently, some interviewees suggested modifying the intervention to offer alternative options to the group walks.

Between group outcomes

Primary RCT outcome: Quality of life

Whilst at baseline the control group reported lower median FACT-G (Functional Assessment of Cancer Therapy- General) QoL scores than the intervention (53 vs 58, respectively), scores were comparable during follow-up (Table 2). Likewise the FACT-G sub-scales scores at T1-T3 were relatively high and stable for both intervention and control groups (Table 2).

Table 2

Primary outcome measure for possible RCT by assessment time and study group

Quality of life	Study group	Baseline Mean (SD) *Median (IQR)*	6 week Mean (SD) *Median (IQR)*	12 week Mean (SD) *Median (IQR)*	24 week Mean (SD) *Median (IQR)*
FACT-G[a] Total score[22]	**Control**	52 (9.1) *53 (11.0)*	51 (11.2) *56(17.5)*	50 (7.9) *52 (13.0)*	48 (12.7) *54 (20.0)*
	Intervention	57 (5.2) *58 (4.0)*	56(6.3) *57 (7.25)*	55 (5.5) *56 (4.0)*	57 (6.9) *56 (10.5)*
Cohen's d effect size (95% CI)		0.67 (0.04,1.28)	0.55 (-0.19, 1.26)	0.73 (-0.07, 1.49)	0.79 (-0.09, 1.62)
Physical well-being sub-scale	**Control**	22(5.8) *24(7.0)*	21 (5.7) 21 (10.5)	22 (5.7) *25 (11.0)*	23 (4.5) *24 (7.5)*
	Intervention	23(4.7) *26 (6.0)*	25(2.4) 26 (4)	25 (3.3) *26 (6.0)*	23 (4.7) *25 (4.7)*
Cohen's d effect size (95% CI)		0.19 (-0.42, 0.79)	0.91 (0.14, 1.64)	0.64 (-0.15, 1.39)	0.00 (-0.82, 0.82)
Social and family well-being sub-scale	**Control**	20 (6.1) *21 (11)*	19 (7.0) 21(10.75)	19 (6.2) *19 (10.0)*	18 (7.3) *20 (12.5)*
	Intervention	22(3.6) *23 (6.0)*	22 (3.9) *23 (6.0)*	22 (4.0) *23 (4.0)*	22 (5.5) *23 (8.0)*
Cohen's d		0.40	0.53	0.57	0.61

Table 2
Primary outcome measure for possible RCT by assessment time and study group

Quality of life	Study group	Baseline Mean (SD) *Median (IQR)*	6 week Mean (SD) *Median (IQR)*	12 week Mean (SD) *Median (IQR)*	24 week Mean (SD) *Median (IQR)*
effect size (95% CI)		(-0.22, 1.00)	(-0.21, 1.24)	(-0.22, 1.32)	(-0.26, 1.43)
Emotional well-being sub-scale	**Control**	17 (5.2) *16 (8.0)*	18 (4.4) *19 (5.3)*	19 (3.8) *19 (6.0)*	20 (3.3) *20 (6.5)*
	Intervention	17 (5.5) *19 (7.0)*	20 (3.6) *20 (4.0)*	20 (3.7) *21 (6.0)*	18 (3.8) *18 (6.2)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	0.50 (-0.24, 1.21)	0.27 (-0.50, 1.02)	-0.57 (-1.39, 0.29)
Functional well-being sub-scale	**Control**	18(5.0) *19 (9.0)*	17 (6.6) *17.5 (10.3)*	19 (6.5) *19 (11.0)*	21 (7.6) *23 (14.5)*
	Intervention	21(6.5) *23 (13.0)*	23(5.6) *26 (8.0)*	23 (4.7) *23 (7.0)*	23 (5.3) *25 (8.0)*
Cohen's d effect size (95% CI)		0.52 (-0.11, 1.12)	0.98 (0.20, 1.71)	0.70 (-0.10, 1.46)	0.30 (-0.54, 1.12)

[a] FACT, Functional Assessment of Cancer Therapy- General

Secondary RCT outcomes

Comparable results for both groups were also found for the secondary outcomes with median scores remaining relatively stable across assessments. Detailed descriptive analysis of subscale scores provide evidence of some floor or ceiling effects (data not shown). For instance, the EQ-5D (health status) showed a clear floor effect with most participants reporting few symptoms at each time point.

The GPPAQ physical activity index (PAI), which includes activity at work, physical exercise and cycling (but not walking), indicated the intervention group was more active at all assessments than the control, and physical activity levels for both groups declined over the study period. However, the GPPAQ item which measures walking activity indicated that the proportion of participants doing at least 3-hours of walking a week increased in both groups (Table 3).

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
Global fatigue score[23]	**Control**	36(21.6) *31 (28.0)*	35 (22.0) *43 (37.0)*	32 (21.9) *26 (40.0)*	28 (24.5) *18 (47.5)*
	Intervention	32 (22.3) *33(43.0)*	18 (15.9) *15 (24.0)*	23 (17.3) *25 (33.0)*	29 (19.1) *31 (24.7)*
Cohen's d effect size (95% CI)		-0.18 (-0.78, 0.43)	-0.89 (-1.61, -0.11)	-0.45 (-1.20, 0.32)	0.04 (-0.78, 0.87)
Exercise self-efficacy[24]	**Control**	28 (6.0) *29(9.0)*	29 (5.5) *29 (6.0)*	29 (4.6) *30 (6.0)*	29 (5.0) *28 (4.5)*
	Intervention	30 (6.0) *31 (8.0)*	33 (5.2) *33 (10.0)*	33 (5.4) *36 (10.0)*	34 (4.6) *34 (8.25)*
Cohen's d effect size (95% CI)		0.33 (-0.28, 0.94)	0.75 (-0.01, 1.71)	0.80 (-0.01, 1.56)	1.01 (0.10, 1.84)
Stress total score[25]	**Control**	9(9.0) *6(12.0)*	8 (9.1) *5 (9.5)*	4 (4.7) *4 (8.0)*	9 (9.5) *8 (0-26)*
	Intervention	8(9.7) *2 (18.0)*	4 (5.1) *4 (6.0)*	5 (5.9) *4 (10.0)*	3 (3.6) *2 (6.0)*
Cohen's d effect size (95% CI)		-0.11 (-0.71, 0.50)	-0.54 (-1.26, 0.20)	0.19 (-0.57, 0.94)	-0.76 (-1.59, 0.11)
Anxiety total score[25]	**Control**	6(5.3) *6(6.0)*	5 (5.4) *4 (6.5)*	3 (3.1) *2 (6.0)*	6 (8.3) *2 (9.0)*
	Intervention	4 (7.1) *2 (4.0)*	2 (3.3) *0 (2.0)**	4 (6.0) *2 (4.0)*	2 (2.7) *0 (5.0)*
Cohen's d effect size (95% CI)		-0.32 (-0.92, 0.30)	-0.67 (-1.39, 0.08)	0.21 (-0.55, 0.96)	-0.60 (-1.42, 0.26)
Depression total score[25]	**Control**	8(7.2) *6 (11.0)*	8 (8.4) *2 (14.0)*	5 (6.5) *2 (9.0)*	8 (9.0) *2 (13.0)*
	Intervention	8(10.1) *6 (15.0)*	3 (4.9) *0 (4.0)**	4 (5.9) *0 (6.0)*	4 (5.7) *2 (9.0)*

Table 3
Secondary outcome measures possible RCT by assessment time and study group

Measures	Study group	Baseline Mean (SD) *Median (range)*	6 week Mean (SD) *Median (range)*	12 week Mean (SD) *Median (range)*	24 week Mean (SD) *Median (range)*
Cohen's d effect size (95% CI)		0.00 (-0.60, 0.60)	-0.73 (-1.43, 0.03)	-0.16 (-0.91, 0.60)	-0.52 (-1.33, 0.34)
EQ-5D score[26]	**Control**	2 (0.66) *2 (1.0)*	2 (0.5) *2 (1.0)*	2 (0.6) *1 (1.0)*	1 (0.5) *1 (0.7)*
	Intervention	1 (0.52) *1 (1.0)*	1 (0.4) *1 (0.8)*	1 (0.4) *1 (1.0)*	1 (0.4) *1 (0.6)*
Cohen's d effect size (95% CI)		-1.68 (-2.35, -0.95)	-2.21 (-3.05, -1.25)	-1.95 (-2.80, -0.98)	0.00 (-0.82, 0.82)
EQ-VAS Your health today score out of 100[26]	**Control**	72 (22.6) *80 (40)*	82 (12.1) *78 (20.3)*	76 (26.4) *90 (41.5)*	79 (19.6) *80 (31.0)*
	Intervention	75 (17.0) *70 (30)*	84 (12.8) *85 (20.0)*	78 (18.1) *80 (28.8)*	81 (14.9) *80 (25.0)*
Cohen's d effect size (95% CI)		0.15 (-0.46, 0.75)	0.16 (-0.56, 0.87)	0.09 (-0.67, 0.84)	0.17 (-0.67, 0.99)
Active/ moderately active[27]		**N (%)**	**N (%)**	**N (%)**	**N (%)**
	Control	2 (10)	0	1(7)	0
	Intervention	6(29)	5 (34)	4 (31)	2(20)
Walked 3 ≥ hours in last 7days[27]	**Control**	9 (47)	7 (54)	11 (79)	9 (82)
	Intervention	9 (43)	9 (70)	7 (58)	5 (62)

In contrast, interview data showed that the intervention group felt that they benefited in terms of physical, emotional and psychological, social wellbeing and lifestyle changes (see Table 4 for illustrative quotes). Most participants reported being previously active and understood the benefits of being more physically active. On the ESQ, 7 out of 10 of the intervention group reported they had set physical activity goals at baseline which they achieved by 24-weeks. In interviews, all participants in the intervention group and 3 out of 5 in the control group reported being more active by 24-weeks.

Wellbeing and lifestyle benefits, such as weight loss, also motivated participants to increase the amount they walked. They spoke about how it improved their overall quality of life and helped them maintain a positive attitude towards their illness. Many participants in the intervention group spoke of the social benefits of participating in the WfH groups (Table 4 for illustrative quotes).

Table 4 Participants views and experiences of the intervention

Theme	Illustrative comments
Physical benefits	*Its praises should be sung more widely, it really would deserve that. It had a revolutionary effect on me. I'm a walking bore now I'm afraid! It was just the right thing at just the right time for me. I think more about walking now, I think can I walk there instead of catching the bus. It's a fairly painless way of keeping weight down while still eating a little bit of what you enjoy….* (3022 male, prostate cancer no pedometer) *I have walked ever since at least 3 days a week. This study has stimulated me. I drop my daughter off at school then go with the dog for a long walk. I have noticed the difference physically. I am back on chemo now and have noticed differences with side effects compared to last year. Last year I had oedema which I don't this time and I just feel a lot fitter this time round. In general, I have a little more stamina than before.* (5016, male, haematological cancer, with pedometer)
Emotional/ Psychological wellbeing	*I would definitely recommend it, particularly to people who are not actively sporty or for sedentary people. Being diagnosed with cancer is a pretty devastating thing and being told its terminal is even more devastating and when I'm on the walks I forget about the cancer, they have helped me enormously by keeping me physically fit and keeping me well but also mentally. I bang on a lot less to those around me about dying than I used to. And that's got to be good for them as well.* (3022, male prostate cancer)
Social benefits	*I have been doing Nordic walking [WfH] at least once a week - it has made a huge difference to me physically and mentally. It makes me do more than I would if I was walking on my own, I have met all sorts of people and as I live on my own it's great being out and meeting other people.* (4065, female gynaecological cancer with pedometer)

Table 4 Participants views and experiences of the intervention	
Theme	Illustrative comments
Wellbeing and lifestyle benefits	*The impact has been immense! Gave me the motivation to not only increase walking activity from minute to 3-4 hours per week but also to reduce weight to desired 77-80kg by altering diet/ reducing sweets/sugars. Great boost to morale-no longer dwell on being terminal - just on getting on with making life as enjoyable as possible, greatly helped by friends made on regular 'walks for life'.* (3022, male, prostate cancer)
Barriers to group walks	*There was only one walk I could find locally that lasted more than 30 mins and seemed to cover a reasonable distance. I turned up to meet and they were meeting in the tea room. I know this sounds a bit ridiculous but I wanted to see who was in the group rather than going straight in. It seemed that everyone in the group was quite a bit older than me, and they spent the first 20mins of the walking time drinking tea in the cafe. When they moved off they were walking quite slowly. I'm not criticising the validity of these social group walks but I was looking for something a bit more energetic, and with people closer in age to me* (8003, male, colorectal cancer).

DISCUSSION

This study aimed to assess the feasibility and acceptability of a RCT of a community-based walking programme in people with recurrent/metastatic cancer. Our results indicate that most self-initiated walks were acceptable, though some reported being unable to commit to the WfH groups regularly, largely due to work commitments. The CanWalk intervention, based on the UK's NICE (National Institute for Healthcare and Clinical Excellence) guidance for promoting physical activity,[15,28] includes active components identified as helping individuals change their behaviour,[16] such as goal setting, planning and social support. However, it is possible that including more monitoring and tailored feedback could be beneficial and could be offered remotely through the use of apps and/or websites. This is supported by comments from

participants from both the intervention and support groups indicating they found completing the outcome measures stimulated them to increase their physical activity levels.

Key elements of feasibility testing have been identified by Bowen et al (2009) [29] and are used (highlighted in bold) here to evaluate whether the CanWalk intervention warrants further investigation. A central focus to our study involved estimating **demand** for the intervention. Forty per cent of those eligible to participate in the study consented. This is comparable to recruitment rates reported in similar studies, [30] and not unexpected in a population comprising people with advanced cancer. Almost a third withdrew within 6-weeks, which is higher than found in previous research, however these studies those with early stage cancer [32] or had shorter follow-ups (4-weeks) [30,31] Our preliminary evidence indicated an association between withdrawal and higher baseline anxiety. This warrants further exploration and consideration of ways the intervention could be made more appealing and acceptable for people with symptoms of anxiety, perhaps through a buddy system or by enhancing the motivational interview component with 'booster' follow-up sessions.

This feasibility study also explored the **implementation** of the study and intervention. Importantly, based on the study data, a power calculation was performed for target recruitment for a future trial. However, the proposed recruitment estimate was not feasible within the timeframe; despite extending recruitment and widening the eligibility criteria to include other diagnoses.

For clinicians to change their practice, they require evidence of the **practicality** of the interventions ie that they can be delivered within existing means and resources.[29] The complementary components of the intervention promoted physical activity. The researchers spent approximately 20-minutes per person delivering CanWalk. This suggests that if the intervention proves effective, it is could be sufficiently brief for delivery by health care professionals in the clinical setting.

Limited-efficacy testing gives an indication of the likely impact of the intervention, although not the primary aim of a feasibility study. Results suggest few differences between groups across the outcome measures at any time point. Arguably, this inability to detect change could be attributed to the small sample size, as the pilot study was insufficiently powered to detect subtle differences. Further, similar to other studies [30,31,33] contamination may have occurred whilst assessing activity levels using outcome measures which reportedly stimulated *all* participants to engage in physical activity. Likewise, participants highlighted that using pedometers with both groups had a similar effect. This suggests an alternative method of assessing walking behaviour is required.

Detailed descriptive evaluation of the performance of the outcome measures suggests that whilst being reliable, some of the measures may not be sensitive to change as they demonstrated floor/ceiling effects. Moreover, feedback from the ESQ and interviews suggested social support was a key perceived benefit of participating in the WfH walks, but this was not reflected in the FACT-G social wellbeing sub-scale scores. However,

this may be because it focuses entirely on support from family and relatives and so would not be sensitive to benefits from making wider social contacts. It will therefore be important to include a brief social support and engagement measure (such as the Duke-Social Support Questionnaire)[34] in future research. Our findings demonstrate the importance of pilot testing questionnaires. As many participants reported the SPAQ was time consuming and confusing suggesting a need to use other measures of physical activity for both measuring adherence to the intervention and outcomes. Pedometer data were often not returned thus alternative methods for measuring the intensity, duration and frequency of physical activity in any future study are recommended. Whilst accelerometers have been used in previous studies they often require expert knowledge to interpret and analyse results, so the use of off-the-shelf wearable technologies may offer an alternative and more cost-effective approach. [35]

Some participants were, from the outset, already active which contributed to difficulty in detecting between group changes. Thus it may be preferable to only recruit people who are judged to be inactive. However, this will reduce the number eligible to participate and exclude people who, although active, wish to increase the amount they walk.

Based on the study findings a number of **adaptations** are proposed for a future study including the refinement of the study samples to include different comparison groups, for example, a tailored CanWalk intervention and written information only group. Furthermore, it will be important to ensure outcome measures used match the benefits reported by participants in the interviews, such as feeling fitter and having more stamina

(e.g. functional walking/fitness tests such as incremental shuttle walk or 6-minute walk test; being less inactive (e.g. measure of sedentary behaviour), weight loss (e.g. weight, body mass index, hip to waist ratio) and symptom control.

Several limitations were identified in the study. The recruitment centres were London-based thus limiting generalisability. Although we were able to collect reasons for non-participation, unfortunately we were not able to collect data on the demographic or clinical characteristics of those who declined participation. Further, the qualitative sample was small, limiting the extent of in-depth analysis of participants' perceptions and experiences. Another limitation is that the views of participants from Black and minority ethnic groups are underrepresented as the study recruited primarily Caucasian participants and English speakers.

Conclusions

This study investigated the feasibility and acceptability of undertaking a RCT of a community-based walking programme to enhance QoL in people with recurrent or metastatic cancer. Results are encouraging and demonstrate that exercise was popular and conveyed benefit to participants. However, further exploration of the intervention is required to refine and understand its components and enhance its capacity to create measurable change.

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Contributorship statement: VT and JH recruited participants and were responsible for day-to-day study coordination, delivery of the intervention and drafted the manuscript. JA is the study chief investigator and provided the concept, hypotheses, study design and methods, recruitment of participants, is responsible for the overall study management and drafted and critically revised the manuscript. ER, MVH, AP, LM, JG and JF participated in the design of the study, critically revised the protocol and the manuscript. All authors read and approved the final manuscript.

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Figure legends:

Figure 1. Flow of participants through the study

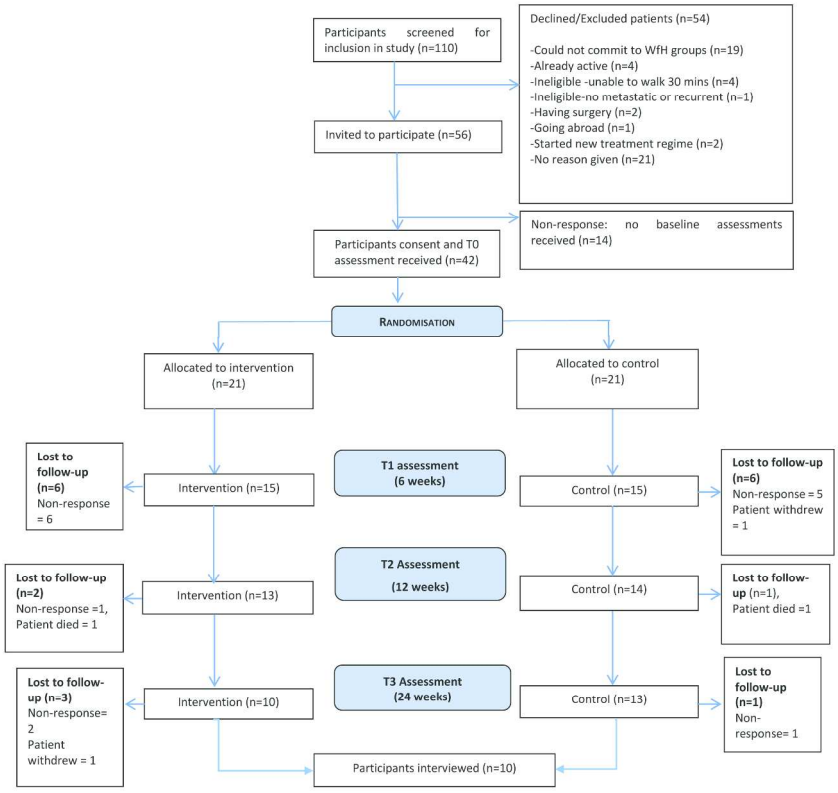

Figure 1. Flow of participants through the study

210x297mm (300 x 300 DPI)

Online supplementary information

Appendix 1
Summary of findings using ADePT methodological issues for feasibility research

Methodological issues	Findings	Evidence
1. Did the feasibility study allow a sample size calculation for the main trial?	Achieved	42 of the target of 60 participants achieved in feasibility study. 108 participants would need to be randomised to each group for the main trial.
2. What factors influenced eligibility and what proportion of those approached were eligible?	Mainly due to refusal to participate	Reasons provided included being: -unable to commit to WfH groups (n=19) -physically active already (n=4) -Ineligible -unable to walk 30 mins (n=4) -Ineligible-no metastatic or recurrent (n=1) -Having surgery (n=2) -Going abroad (n=1) -Started new treatment regime (n=2)
3. Was recruitment successful?	Recruitment was fairly successful.	42/105 screened participants. This is reasonable for a physical activity feasibility study including people with recurrent and metastatic cancers.
4. Did eligible participants consent?	Consent of eligible participants was good.	42/56 patients who were provided with the baseline questionnaire and consent returned these.
5. Were participants successfully randomized and did randomization yield equality in groups?	Randomization procedures worked well and equality in groups for age and sex were achieved. However, the control group were far more active at baseline suggesting the minimisation criteria of walking 3 hours each week was not sensitive enough (because some participants engaged in other physical activity).	21 men and 21 women with comparable distribution between control and intervention. Mean and median age in both groups was comparable and representative of the target population. Equal numbers of participants in each group walked for at least 3 hours, however 6 of the control group were classed as 'active' compared with 2 in the intervention group.
6. Were the blinding procedures adequate?	Not applicable.	

Appendix 1
Summary of findings using ADePT methodological issues for feasibility research

7. Did participants adhere to the intervention?	Adherence for those who were randomised to the intervention was good; however, some participants adapted the intervention.	Questionnaires and interviews. Participants took part in the walking groups during the 12 week period. Some continued with these groups and others continued to walk on their own or with friends/family
8. Was the intervention acceptable to the participants?	The intervention was mostly acceptable.	Questionnaires and interviews. Overall participants enjoyed taking part. One younger participant withdrew because he did not think the walking groups were age appropriate.
9. Was it possible to calculate intervention costs and duration?	Partially achieved.	The MI intervention lasted 10-15 minutes. Full costs should be included in future RCT.
10. Were outcome assessments completed?	Completion of outcome assessment was good between baseline and 12 weeks (intervention period). Attrition was more evident at 24 weeks.	Baseline: 42 questionnaires/ 14 pedometer logs completed 6 weeks: 30 questionnaires/ 11 pedometer logs completed 12 weeks: 27 questionnaires/ 9 pedometer logs completed 24 weeks: 23 questionnaires/ 8 pedometer logs completed
11. Were outcomes measured those that were the most appropriate?	Partially.	Although good internal reliability was indicated (Cronbach α >0.80) there was evidence of ceiling/floor effects. SPAQ was found to be unacceptable to participants with inadequate data quality.
12. Was retention to the study good?	After an initial withdrawal after randomisation 6 to 12 week retention was good. Retention was reasonable at 24 weeks for a physical activity feasibility study including people with recurrent and metastatic cancers.	See outcome assessment above (10).
13. Were the logistics of running a multicentre trial assessed?	Some clinics were better at recruiting than others but both hospital sites recruited.	Feedback from site staff suggests that dedicated research nurses or researchers based at each hospital are recommended for the main RCT. Recruitment was easier when researchers attended all relevant clinics.

Appendix 1 Summary of findings using ADePT methodological issues for feasibility research		
14. Did all components of the protocol work together?	All components of the protocol worked well.	No difficulties identified in processes or implementation by the researchers or site staff (research nurses/clinicians).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Completed for CANWALK: A RANDOMISED FEASIBILITY TRIAL OF A WALKING INTERVENTION FOR PEOPLE WITH RECURRENT OR METASTATIC CANCER.

Please note the feasibility/pilot RCT COSORT statement is not yet available and so we have completed the standard CONSORT checklist.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1, feasibility randomised trial
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	7 (note feasibility RCT)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	n/a
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	11, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a (feasibility trial)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11-13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13-15, 19-21
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21- 25

Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.