

Process evaluation of an app-based intervention with behavioural support to promote brisk walking in people diagnosed with breast, prostate, and colorectal cancer (APPROACH)

Fiona Kennedy, Susan Smith, Rebecca J Beeken, Caroline Buck, Sarah Williams, Charlene Martin, Phillippa Lally, Abi Fisher

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Abstract

Background: The APPROACH pilot study explored the feasibility and acceptability of an app (National Health Service [NHS] Active 10) with brief habit-based behavioural support calls and print materials intended to increase brisk walking in people diagnosed with cancer.

Objective: Following UK Medical Research Council guidelines, this process evaluation assessed implementation of the intervention, examined the mechanisms of impact and identified contextual factors influencing engagement.

Methods: Adults (>18 years) with breast, prostate or colorectal cancer who reported not meeting the United Kingdom (UK) guidelines for moderate to vigorous physical activity (MVPA; >150 mins/week) were recruited from a single hospital site in Yorkshire, UK and randomised to intervention or control (usual care) and assessed via quantitative surveys at baseline (T0) and 3 month follow-up (T1) and qualitative exit interviews (n=36:82%) at T1. The process evaluation included intervention participants only (n=44). Implementation was assessed using data from the T1 questionnaire exploring use of the intervention components. Perceived usefulness of the app, leaflet, and behavioural support call was rated 0-5. Behavioural support calls were recorded and the fidelity of delivery of 25 planned behaviour change techniques (BCTs) were rated 0-5 using an adapted Dreyfus scale. Mechanisms of impact were identified by examining T0 and T1 scores on the Self-Reported Behavioural Automaticity Index and feedback on the leaflet, app, call, and planner in the T1 questionnaire and qualitative interviews. Contextual factors influencing engagement were identified through qualitative interviews.

Results: Implementation of the intervention was successful: 98% received a behavioural support call, 78% reported reading the leaflet, 96% reported downloading the app, and 83% reported using the planners. The mean perceived usefulness of the app was 4.3 (SD=0.8) in participants still using the app at T1 (n=33). Participants rated the leaflet as useful (M=3.9, SD =0.6) as well as the behavioural support call (M=4.1, SD =1.0). The intended BCTs in the behavioural support calls were proficiently delivered (Overall M=4.2, SD=1.2). Mechanisms of impact included habit formation, behavioural monitoring, and support and reassurance from the intervention facilitator. Contextual factors impacting engagement included barriers such as the impact of cancer and its treatment and facilitators like social support.

Conclusions: The APPROACH intervention was successfully implemented and shows promise for increasing brisk walking potentially through promoting habit formation and enabling self-monitoring. Contextual factors will be important to consider when interpreting outcomes in the larger APPROACH randomised controlled trial. Clinical Trial: 18063498

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Original Manuscript

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Keywords

Cancer, Physical activity, Process Evaluation, Randomised controlled trial, Intervention, App, Habit.

Introduction

The number of people being diagnosed with cancer is continuing to increase in the United Kingdom (UK), with an estimated 4 million adults living with and beyond cancer (LWBC) by 2030 (1). Therefore, the importance of improving outcomes for those LWBC is vital (2). A large body of trial data demonstrates that physical activity (PA) improves a number of outcomes after a cancer diagnosis, including reduced fatigue, pain, anxiety, depression, sleep problems and an overall improvement in quality of life (3-6). Observational data suggest that PA is also associated with improvements in survival (7-9). In light of this ever-growing evidence base, the World Cancer Research Fund (WCRF) recommends that people LWBC follow the guidelines for healthy populations in achieving at least 150 minutes of moderate to vigorous physical activity (MVPA) per week and recommend limiting the amount of time spent sedentary (10). Despite this, many people LWBC are physically inactive, with Macmillan Cancer Support (UK) estimating this to be as high as 80% of those LWBC not meeting recommended PA levels (11). This is supported by Wong and colleagues' systematic review of 41 studies that indicated that only around a third of people LWBC were meeting PA guidelines, although this ranged across studies from 16-88% (12).

The APPROACH Intervention

APPROACH is an app-based multi-component intervention informed by extensive development work with both individuals with breast, prostate and colorectal cancer, and cancer nurse specialists (13, 14). It focuses on promoting and monitoring brisk walking using a publicly available mobile phone app, alongside brief behavioural support in the form of a specially designed leaflet, walking planner cards, and two phone/video calls with a trained researcher (CB) (15). In line with the Medical Research Council (MRC) framework for intervention development and evaluation, the pilot trial explored the feasibility and acceptability of conducting a complex PA intervention trial with people LWBC. Ninety people diagnosed with breast, prostate or colorectal cancer were recruited for

the pilot RCT with 44 randomised to the intervention group and 46 to the control group. APPROACH pilot results demonstrated a high retention rate (97%) and high assessment completion rates (>86%) indicating that the trial procedures were feasible and acceptable to be carried out as intended in a confirmatory phase III larger trial (16). Additionally, results showed that the intervention was delivered successfully with 98% receiving at least one behavioural support call and 96% of participants downloading the app (16).

Conducting a process evaluation

The importance of conducting process evaluations within RCTs has been emphasised to explore the way in which any complex intervention is implemented (17, 18). This can help uncover why interventions are successful or unsuccessful, why they may have unexpected consequences as well as exploring how an intervention that is effective can be optimised (17). Moore and colleagues provide specific guidance for carrying out process evaluations, which highlights the importance of exploring the implementation (e.g. fidelity of intervention calls), the mechanisms of impact (e.g. views on the different components of the intervention), and the contextual factors influencing use and/or outcomes (e.g. barriers/facilitators to engagement) (19).

Therefore, this paper extends the published APPROACH feasibility results (16) with the following aims:

- To evaluate the implementation of the APPROACH intervention and the fidelity of the delivery of intended behavioural change techniques;
- 2. To identify the potential mechanisms of impact that underlie behaviour change attributed to the APPROACH intervention:
- 3. To better understand how contextual factors influence engagement with the APPROACH intervention

Methods

Design

The process evaluation mixed methods data collection was embedded within the APPROACH pilot RCT (15, 16). The pilot RCT compared an app-based brisk walking intervention delivered alongside usual care, with a control arm (usual care alone) in people diagnosed with breast, prostate, or colorectal cancer at a single hospital site. The primary outcome for the pilot and future RCT is weekly minutes spent brisk walking (a cadence of 100 steps per minute or more (20, 21)). Following baseline assessments, participants were individually randomised (1:1 allocation) using minimisation to either the control or intervention arm, stratified by cancer type (breast, prostate, colorectal) and disease status (advanced/metastatic versus not).

Participants

The pilot RCT included 90 participants: 44 in the intervention arm and 46 in the control arm. All participants had a confirmed diagnosis of breast, prostate, or colorectal cancer (localised or metastatic). At the point of screening, localised participants had to be within 6 months of completion of radical treatment, and all participants self-reported achieving less than 150 minutes of MVPA weekly. Full inclusion/exclusion criteria have been published previously (15).

Procedure and description of intervention

The recruitment procedure and trial data collection have previously been described (15, 16). Participants completed assessments at baseline (T0) and three months (T1; operationalised as 12-16 weeks post randomisation). The intervention included an endorsed letter from a member of their clinical team, alongside the provision of a leaflet with information about importance of PA after cancer and a recommendation and instructions on how to download the freely available NHS Active 10 app. The Active 10 app promotes brisk walking in bouts of 10 minutes, called 'Active 10s'. This

was augmented with two behavioural support phone/video calls with the intervention facilitator (CB). These behavioural support calls were underpinned by habit theory (22) and behaviour change techniques (BCTs) shown to be effective in promoting PA (23-25) and involved supporting participants in downloading and using the app and discussions around setting PA goals. The intervention calls took place over Zoom (26) or by telephone and were recorded by the intervention facilitator with the participants' permission. Participants were asked during the first intervention call if they had downloaded the Active 10 app and the intervention facilitator noted this in their records. Participants were also given 12 copies of a walking planner card that was designed to enable them to plan how many 'Active 10s' they were aiming for and how they were going to achieve these, including where and when they would complete them.

Implementation of the APPROACH intervention

Delivery of the intervention

The implementation of the intervention was explored by looking at whether each component was delivered as intended and participants' use of each intervention component. Between 12-16 weeks post-randomisation participants completed the T1 questionnaire. Participants were asked about the intervention, including: whether they downloaded the app (yes/no), their self-reported app usage if still using the app (less than monthly/monthly/fortnightly/weekly/3-4 times a week/almost every day or every day), how long they used the app for if they had stopped using it (never/once/less than monthly/fortnightly/weekly/3-4 times per week/almost every day or every day), perceived accuracy of the app in recording their time spent walking (5-point scale from not accurate to very accurate), whether they read the leaflet (all/some/did not read), used the walking planner cards (yes/no) and received either behavioural support call (yes/no).

Usefulness of intervention components

Participants rated the usefulness of the call for going through the leaflet information, downloading the app, and thinking about ways to use the app to increase their brisk walking (5-point scale from not at all useful to extremely useful). Using the same scale, they rated the usefulness of the app and sections of the leaflet for supporting their walking.

Delivery fidelity of behavioural support calls

The recorded intervention calls were coded by one researcher (SW) to assess delivery fidelity. All calls were listened to and coded according to a 25-item checklist of BCTs (25) as presented in the study's protocol paper (15). Each item represented a BCT paired with the intended delivery technique (Table S1). If a participant received two calls, these were combined when coding delivery of the BCT. A 5-point rating scale was applied to the fidelity checklist using an adaptation of the Dreyfus scale (27) (28) ranging from 'low fidelity' (0) indicating that the facilitator did not mention the intended BCT at all, to 'expert' (5) indicating that the facilitator delivered the BCT to an exceptional standard (Table S1, Multimedia Appendix 3). A value of 3 or higher represented 'competent delivery' of an individual BCT, thus presenting successful delivery. A second researcher (SS) coded a subset of interviews (n=5). It was agreed that if there was a discrepancy of over 20% in the coding then the transcript would be discussed amongst the researchers. This occurred for one transcript that was double coded. This iterative process enabled SW to incorporate any learnings from the discussion into the coding of all transcripts and allowed for a more consistent coding of the data.

Mechanisms of impact and contextual factors influencing engagement

T0 and T1 questionnaires

Habit strength for walking ('going for a walk' and 'walking briskly') was assessed using the Self-

Report Behavioural Automaticity Index (SRBAI (29)) in the T0 and T1 questionnaires. Participants responded on a 7-point scale from 'Disagree' to 'Agree' to four statements on their perceived automaticity of performing the behaviour. An average score across items was calculated representing the level of automaticity for the behaviour being measured. Higher average scores indicate stronger habit or greater automaticity (29). The SRBAI is presented in Multimedia Appendix 1. Mechanisms of impact and contextual factors impacting engagement were also identified by examining responses to the T1 questionnaire about the delivery of intervention components and their perceived usefulness.

Qualitative interviews

Participants were asked in the initial study consent form if they were agreed to being invited to participate in a semi-structured interview at the end of the study. After the completion of all other data collection at T1, all participants who agreed were invited to be interviewed. Two members of the research team (SS and FK) carried out the interviews. SS and FK were involved in organising assessments with participants throughout the pilot RCT. The interviews followed a topic guide exploring trial procedures and participants were asked to give feedback on the intervention components (available in Multimedia Appendix 2). Interviews took place over the phone and with the participants' permission were audio-recorded and transcribed verbatim. Contextual factors were explored in the interviews and were described in terms of barriers and facilitators of engaging with the intervention.

Data analysis

Implementation of the APPROAHC intervention

The T1 questionnaire responses on intervention components were explored descriptively by calculating percentage frequencies, and where relevant, measures of central tendency. Mean scores were calculated for the delivery of each BCT in the intervention calls, as well as an overall mean fidelity score for each call.

Mechanisms of impact and contextual factors influencing engagement

The data from the questionnaires and interviews were pooled to investigate the mechanisms of impact and contextual factors of intervention engagement. The SRBAI results from the T0 and T1 questionnaire were explored descriptively using medians and interquartile ranges due to the skewness of the data. The T1 questionnaire responses on intervention components were also used to identify mechanisms of impact.

Three authors (SW, FK, SS) analysed the data from the qualitative interviews using thematic analysis (30, 31). Inductive coding was undertaken, with these codes then used to develop themes, and early and final themes discussed throughout amongst multiple authors (FK, SS, PL). While initial coding was inductive and focused on identifying commonalities across the transcripts, final theme development was also organised by focusing on the outlined process evaluation aims on exploring the delivery of the intervention, the mediating processes (mechanisms of impact) and the barriers and facilitators to engagement (contextual factors). All interview transcripts were managed in NVivo (version 12) to facilitate analysis and data management.

Results

Table 1 presents the sample characteristics of the 44 participants in the intervention arm. Participants were mainly of white ethnicity (96%; 42/44), comprised equal males to females (50%; 22/44), with a mean age of 63 (SD=11), ranging from 40-85 years. Participants had received a diagnosis of breast (41%; 18/44), prostate (41%; 18/44), or colorectal (18%; 8/44) cancer.

Table 1. Characteristics of the APPROACH intervention group (N=44)

Characteristics	N (%)
Gender	
Male	22 (50.0)
Female	22 (50.0)
Age (years)	
40-50	7 (15.9)
51-60	10 (22.7)
61-70	14 (31.8)

IR Preprints		Kennedy et al
71-80	12 (27.3)	
81+	1 (2.3)	
Ethnic Group	1 (=.5)	
White	42 (95.5)	
Asian	1(2.3)	
Black	0 (0.0)	
Mixed	0 (0.0)	
Other	1 (2.3)	
Cancer type		
Breast	18 (40.9)	
Prostate	18 (40.9)	
Colorectal	8 (18.2)	
Localised/Metastatic		
Localised	41 (93.25)	
Metastatic	3 (6.8)	
Relationship Status		
Married/in a relationship	37 (84.1)	
Single/divorced/separated	3 (6.8)	
Widowed	4 (9.1)	
Employment		
Full time	8 (18.2)	
Part time	9 (20.5)	
Unemployed	2 (4.5)	
Retired	22 (50)	
Unable/too ill to work	3 (6.8)	
Living arrangements		
Alone	5 (11.4)	
With partner	25 (56.8)	
With family	14 (31.8)	
Index of Multiple Deprivation Quintile		
n(%)		
1 (most deprived)	8 (18.2)	
2	6 (13.6)	
3	9 (20.5)	
4	16 (36.4)	
5 (least deprived)	5 (11.4)	

Implementation of the APPROACH intervention

Two participants withdrew from the intervention group for reasons unrelated to the intervention (frustration with the accelerometer and increased caring responsibilities; 5%; 2/44). Most participants who remained on study answered the section of the T1 questionnaire on intervention feedback (98%;

41/42). One participant did not complete this section on intervention feedback (1%; 1/42).

Delivery of the intervention

Leaflet

In the T1 questionnaire, 78% (32/41) of intervention participants reported reading all the intervention leaflet while 10% (4/41) reported reading some of it, and 12% (5/41) reported not reading it at all. Of those who did not read it at all, four stated that they did not remember receiving the leaflet and one stated that it was not relevant to them.

Active 10 app

At the time of the first behavioural support phone call, the intervention facilitator recorded that 96% (42/44) participants had downloaded the Active 10 app, with 39 independently downloading it before the first intervention call and three downloading it during the call. One participant left call 1 not having downloaded it. In the T1 questionnaire, 95% (39/41) of intervention participants self-reported successfully downloading the app.

Two participants were not asked about their use of the app as they reported not downloading the app earlier in the questionnaire. Most participants reported still using the app (85%; 33/39). Of these, 82% (27/33) reported using it 'almost every day or every day' and 18% (6/33) reporting that they use it '3-4 times per week'. Five participants reported using the app during the study but were no longer using it (12%; 5/41). When asked how long they had used it for, the five participants reported using it for '1 week', '2 weeks', '1 month', '2 months', and '3 months'. One participant reported not using the app at all despite downloading it.

Planner cards

In the T1 questionnaire, 83% (34/41) reported using the walking planner cards, whereas 17% (7/41) did not, including one participant who said they did not receive any cards. Other non-use was mainly

explained in terms of not finding it helpful/not needing to plan (12%; 5/41) or having a more physical job (2%; 1/41). Of those who used the planners, 65% (22/34) reported using the planners for the full 3 months, whereas others reported using for 2 weeks (12%; 4/34), 1 month (12%; 4/34), or 2 months (12%; 4/34).

Usefulness of intervention components

Perceived usefulness of the intervention components is presented in Table 2 along with perceived accuracy ratings for the Active 10 app in Table 3.

Table 2. Perceived usefulness of the APPROACH intervention components^a (Total

TA 1	1 1	1	`
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1.1			•

(1.0) an n	
(1.0) 40 ^b	
(1.0) 40^{b}	
(0.9) 36°	
(0.8) 36°	
(0.8) 36°	
(0.8) 36°	
(0.7) 36^{c}	
(1.5) 36^{c}	
(0.6) 36°	
(0.8) 33 ^d	
(U 0) Eq	
(0.3)	
•	0.9) 5 ^d

^bOne person reported not receiving a behavioural support call and was not shown this

question.

^cFive people reported that they had not read the leaflet and were not shown these questions.

^dOne participant reported downloading but never using the app to track their walking.

Note: Perceived usefulness of the walking planner card was not explored in the T1 questionnaire.

Table 3. Perceived accuracy of the app in tracking walking^a (Total N=41)

Table by a creery of the app in true in a warming (10th 11 11)							
Perceived ac	Perceived accuracy of Active 10 in tracking walking		king	M (SD) ^a	n		
App accurac	y in particip	ants still usin	g the app		3.9 (1.2)	33 ^b	
App accuracy in participants who had stopped using the		using the	2.2 (0.8)	5^{b}			
app							
^a 5-point	scale	from	not	accurat	e to	very	accurate.

^bOne participant reported downloading but never using the app to track their walking.

Delivery fidelity of behavioural support calls

Forty-three participants received the first behavioural support call (98%; 43/44). Thirty-one of these were conducted on Zoom (72%; 31/43) and 12 by telephone (28%; 12/43). Forty participants received the second call (91%; 40/41). Twenty-two of these were on conducted on Zoom (55%; 22/40) and 18 by telephone (18/40; 45%). In total, 81 intervention calls from 42 participants were included in the analysis (42 first calls and 39 second calls). One intervention participant did not receive any calls and another participant was removed from the analysis due to a recording issue with the first call so neither of their calls were included in the fidelity results. The overall mean delivery fidelity score across all BCTs and all participants was 4.2 (SD=1.2), which demonstrates overall proficient delivery. Eighteen BCTs had a rating of >4 (72%; 18/25), four had a rating of 3-4 (16%; 4/25), and three had a rating <3 (12%; 3/25). The BCT 'Provide information on health consequences' had the highest fidelity (4.98). This was followed by 'Action planning' (4.90) and Habit formation' (4.88). 'Framing/reframing' had the lowest fidelity (1.31). 'Non-specific reward' (2.71) and 'Non-

specific incentive' also displayed low fidelity. The delivery fidelity of each BCT that was intended to be delivered during the calls is presented in Table S2 in Multimedia Appendix 4.

Mechanisms of impact and contextual factors influencing engagement

T0 and T1 questionnaires

All intervention participants completed the SRBAI at baseline (100%; 44/44). All participants who remained on study completed the SRBAI at T1 (100%; 42/42). As above, most participants who remained on study answered the section of the T1 questionnaire on intervention feedback (98%; 41/42).

Qualitative interviews

Of the 42 participants who remained on study, 36 took part in the qualitative interviews (86%; 36/42). Three participants did not give a reason for declining to participate (7%; 3/42) and two participants consented to the interview but then did not respond to the interview invitation (5%; 2/42). One participant did not feel up to taking part in the interview due to illness-related side effects (2%; 1/42).

Mechanisms of impact

Identified mechanisms of impact are outlined below with exemplar quotes indicating the participants' gender (M=male, F=female) and age.

Shapes understanding of PA and its importance

Many participants reported gaining information about brisk walking and its benefits, as well as information on how to use the app through the intervention call and the leaflet:

"the lady basically went through everything. That was probably the most helpful thing. How to use things and everything." (F;42)

"a good overview of what it was about and why you were doing it" (M;59)

The delivery of comprehensive and meaningful information enhanced participants' understanding of the target behaviour and provided them with a clear purpose for implementing it:

"She went thoroughly through the app with me...Then when she started to explain it, I thought yes, that makes sense" (M;60)

Enables monitoring of behaviour

Participants reported that having two intervention calls was motivating as it helped them to reflect on their progress between the calls:

"the follow up call halfway through was touching base and seeing how I was getting on which obviously encouraged me to do it" (M;73)

The feedback on behaviour received through the app showing daily, weekly, monthly minutes of brisk walking was considered effective. Participants reported that they found the tracking feature motivated them to continue their walking efforts:

"Yes, I'm continuing to use it because I'd be able to see how I'm still improving" (F;65)

"And actually, when I realised I wasn't doing enough, when I felt able to, I extend my walk to get the thirty minutes" (F;60)

Several participants reported using the planner cards to record their walks afterwards rather than upfront planning with them. However, this sense of accountability through recording their activity engaged them to keep walking:

"I filled them in when I came back" (F;65)

"I wrote down what was on my app, every day, how many minutes walking I did everyday"
(F;62)

Increases motivation toward rewards

Many participants reported that the app was the primary intervention component that kept them most motivated and engaged, particularly through the trophies/cups awarded (for every 10 minutes of brisk walking):

"I did enjoy getting them cups every day, I thought that were great" (F;61)

"I think is a good little app, it encourages you, you know it dings you to get off your bum and start walking" (M;69)

Participants often reported walking a few more minutes to achieve the next reward/cup on the app, some even referring to being obsessed or addicted to achieving their goals:

"if I get to say 28 minutes, I'll just do the extra two to make it thirty" (F;49)

"30 has been the minimum goal I've gone for. So even if it's not been a nice day or if I'm tired...I still go out...it's addictive" (M;75)

The achievability of these rewards influenced engagement, with several participants reporting exceeding their targets and wishing that more rewards were available:

"That's another downside, you can't set your goal to any more than three" (F;61)

Participants also reported a sense of satisfaction when being able to tick off completing their walks in their planners:

"Its that holding to account bit. That's what it is" (*F*;57)

"you can see something, you're achieving something" (F;47)

Encourages habit formation

Many participants reported feeling that they had formed habits throughout the intervention period and this enabled them to establish and maintain their walking and brisk walking habits:

"So the fact that I did it daily made me do it...Yes and so now I don't have to think about it every day because I just go and do it" (M;65)

It's part of it now, it's part of your day, it's part of your walk so its not I'm going I've got to do this, I've got to do that...It's just a normal day for us going for a walk. And you get back and you think, mmm, I didn't realise I was doing that quick" (F;65)

I did see the benefit of the cards in terms of establishing habits and making me think about that (F;60)

This is also supported by the SRBAI results for 'walking', where total SRBAI scores in the intervention group increased from baseline (M=4.1, SD=1.6) to T1 (M=4.7, SD=1.9). Similarly, total SRBAI scores for 'brisk walking' in the intervention group increased from baseline (M=4.0, SD=1.7) to T1 (M=5.1, SD=1.8).

Providing reassurance and encouragement

Many participants recalled how helpful and friendly the facilitator was in the intervention calls:

"they were lovely, caring and friendly" (F;61)

This positive rapport helped participants in adhering to their brisk walking and they recalled feeling encouraged and supported throughout the intervention period:

"I could tell she was on my side." (M;85)

"it's useful because it makes you feel as if you're not forgotten" (M;73)

Contextual factors

The contextual factors influencing engagement are summarised according to barriers and facilitators with exemplar quotes indicating the participants' gender (M=male, F=female) and age.

Barriers

Flexibility in lifestyle and planning

Data from the qualitative interviews and the T1 questionnaire indicated that participants felt the planners, in their intended use (to plan walks each week), were not flexible enough and didn't fit their lifestyles:

"it didn't work for me at all because every day is different" (F;42)

"difficult to stick to the same time, because of different things that were going on" (*F*;58)

Related to this, some participants suggested making the planners daily, rather than weekly, which would allow more nuanced plans to be made:

"it wasn't going to be at the same time every day so it just needed breaking down into a daily

thing" (F;57)

The impact of cancer and its treatment

Several participants reported in the interviews and the T1 questionnaire that their cancer diagnosis and treatment sometimes made it difficult to engage with the intervention:

"this was just after my treatment and I was tired a bit" (F;67)

"I couldn't plan, because I was in and out of different appointment times" (F;57)

This was also seen when participants were asked about the appropriateness of the app for people LWBC, with several participants reflecting on how differing experiences may help or hinder engagement:

"I had some days where I felt like I didn't want to see daylight, not talk to anybody...I think on those bad days I wouldn't have wanted to be bothered with it" (F;67)

Many participants discussed that the appropriateness of the timing of the intervention would be dependent on where the patient was in their cancer care. Although many participants noted that during treatment would have been too difficult for them due to the side-effects, several also suggested that during treatment was suitable as it gave them something else to focus on:

"No I wouldn't have been able to do it when I was having chemo, I could barely even walk round the garden" (F;58)

Other competing commitments

Several participants reported not having time to walk due to factors such as having caring responsibilities, working hours, and appointments:

"well the kids can't walk with me they have only got little legs, who is going to watch them?"
(F;41)

"at the time I was working nights but it was awkward to find time to do individual exercise" (M;58)

Technical difficulties with the app

In the interviews, several participants reported experiencing difficulties with the recording of walks on the app if there was a lack of signal or due to the phones positioning. For example, sometimes participants found the recording differed depending on what pocket their phone was in:

"if I had it in my trouser pocket by my leg it worked all fine, ok, no problem at all, if I had it in my shirt pocket it didn't register anything" (M;73)

"I might have dropped out. You know because I was thinking you know me wife said, my wife saw that it was having that issue with me that you know I used to come back and I'd say, "It's only recorded eight minutes again and I've been out there 40"." (M;65)

This is supported by the T1 questionnaire results indicating that perceived app accuracy was an issue that likely influenced use and engagement with the app overtime:

"Didn't find the app as accurate as it could be and doubted its recordings on occasions" (F;41)

Environmental influences

Participants described how the weather played an influential role in their ability and motivation to go on their walks:

"What it's going to be like when it starts raining and it's really awful weather I don't know" (F;40)

"I try to get out several times a week to do a good walk, weather permitting obviously" (M;74)

As well as hindering their ability to go out on a walk, some participants also described feeling guilty if they didn't go out and walk due to the weather:

"I'd say the only negative is if it's coming down in buckets, and it's wet all day or inclement weather I still felt I should be going for a walk but I'm not going to get drenched" (M;73)

"There were some days where it was absolutely throwing it down outside...and I thought oh

no and I really felt guilty that I'd not actually done it" (F;61)

Facilitators

Support from others

Many participants talked about telling people of their involvement in the trial and their efforts to increase their walking, describing a sense of accountability from sharing the experience with others:

"so now it's a case of, "Have you got your minutes in yet dad?" and it, everyone's sort of like joining in with it" (M;75)

Additionally, having someone to go on a walk with and even having family members and friends also use the app was described as encouraging and gave participants a sense of comradery in changing their behaviour:

"My partners been using it. She's downloaded it at the same time as myself" (M;60)

"It made us all as a family go for a walk. It not just helped me with that. It helped all of us." (F;42)

Personal contact from the study team also facilitated engagement, with several participants reporting that they felt supported and that they felt they had the opportunity to get in touch if needed:

"it were good to know that somebody you know, I'd phone and they'd take an interest" (F;61)

Trust in healthcare professionals

Several participants noted that endorsement from their healthcare professional facilitated their engagement with the intervention and willingness to change their behaviour, as their medical team are seen as a credible source of information.

"I mean they have got more medical knowledge of these kinds of things" (F;67)

"So the fact it had come from the doctor made me want to do it even more" (F;42)

Perceived usefulness of the intervention

The perceived usefulness of the intervention components appeared to influence engagement in the target behaviour, with participants reporting that some components (e.g., app) were more helpful

than others (e.g., planners).

Overall, the behavioural support call was rated as useful (M=4.1, SD=1) (Table 2). In the qualitative interviews, the participants reported finding the calls useful as a source of information and motivation, as well as helping them to regain their focus:

"You know, if you've got an issue you can talk to somebody about it. But also it keeps you motivated" (F;56)

"But that call halfway through to keep your focus was most helpful" (F;57)

The leaflet was generally rated as useful (mean=3.9, SD=0.6), particularly the sections on 'walking', 'downloading the app' and 'walking habits' (Table 2). The qualitative data suggested that although this was useful for reading initial information about the benefits of brisk walking and particularly for downloading the app, some participants reported limited recollection about the leaflet at the follow-up point:

"I did have a quick flick through it. And obviously the bit about finding the app" (F;49)

"I can't remember but it must have been fine because I downloaded it and it worked alright, I honestly can't remember without diaging it out" (F;47)

T1 questionnaire results indicated a mean usefulness of 4.1 (SD=1) for the app, but with higher ratings amongst the 33 participants still using compared to the five who had ceased. Most of users found it extremely useful or very useful (74%; 28/38). Participants who reported still using the app reported higher perceived accuracy of the app in recording their time spent walking compared to those not using the app anymore (Table 2). This is supported by the qualitative findings, with participants reporting still using the app and finding it enjoyable to monitor their progress on it:

"I still check the app to see how I'm doing" (F;70)

"I use it all the time now...I still want to make sure I have got at least two cups" (M;74)

Usefulness of the planner explored in the qualitative interviews highlighted that although the planners were useful to get started and to form habits, their use ceased over time due to factors such

as not finding planning as helpful long-term, finding the app sufficient to motivate them, and just forgetting to use them:

"I think you need the planner thing for the first week or so but after that I don't think you do" (F;56)

"Well I started filling them out and thought to myself, I'm doing this anyway so what's the point of actually writing it down" (M;78)

Perceived benefits of engagement with the intervention

Where participants felt they were benefiting from taking part, they reported feeling motivated to continue their brisk walking, reporting feelings of enjoyment, better mood/well-being, and improvements in physical health and fitness:

"I definitely felt better in myself, there's no question about that. I felt fitter as well" (M;60)

"It sort of gives you that feel good factor doesn't it going out walking" (F;57)

"I always felt better when I came back from a walk" (M;74)

As well as direct impact of the intervention, many participants also reported feeling more able to engage in activities of daily living such as going shopping, socialising, and doing housework as a result of their improved fitness and wellbeing:

"I have started going out with more friends...getting out a bit more and feel better and everything" (F;67)

"And the more I went out, the more I wanted to go" (F;70)

Discussion

This study combined data collected as part of the APPROACH pilot RCT to assess the implementation of a multicomponent app-based behavioural intervention to promote brisk walking in people LWBC. The findings of this process evaluation demonstrated proficient implementation of the intervention and suggest that there are several mechanisms of impact underlying the efficacy of the intervention, as well as contextual factors that can be barriers or facilitators to engagement.

Successful implementation of the APPROACH intervention

The successful delivery of intervention components and intended BCTs is essential for attributing any changes in behaviour to the intervention in question (32). This study demonstrated proficient implementation with most participants reporting engaging with the intervention components, including downloading the app, reading the leaflet, receiving the behavioural support call, and using the planners. Additionally, fidelity is rarely reported in evaluations of PA interventions (23). This study reports high delivery fidelity of the intended BCTs in the behavioural support calls (16). The BCTs 'Information on health consequences', 'Action planning' and 'Habit formation' showed the highest fidelity and these BCTs appear to influence key mechanisms of impact highlighted by participants in the qualitative interviews. Empowering participants with information on why they should go walking and providing them with information about its benefits appeared to enhance their engagement and adherence to their planned walks. The BCTs that were not successfully delivered included 'Non-specific reward', 'Non-specific incentive' and 'Framing/reframing'. Despite 'nonspecific reward' receiving a low fidelity rating in the recorded behavioural support calls, the qualitative interviews suggested that this BCT was effectively covered in other aspects of the intervention with participants reporting enjoying working toward the rewards and trophies in the Active 10 app. The low delivery fidelity of 'Framing/reframing' could be attributed to participants' voluntary enrolment in a PA trial. It is likely that they already recognised the importance of PA even

without fully recognising its role in life beyond a cancer diagnosis (33, 34).

Behavioural change techniques underlying change

The mechanisms of impact identified by participants in the qualitative interviews and follow-up questionnaire were in line with previous research. For instance, self-monitoring of behaviour is one of the most frequently employed components in complex PA interventions (35) and multiple systematic reviews have demonstrated its effectiveness in increasing PA that is maintained long-term (36-38). In this intervention, the Active 10 app allowed participants to track their brisk walking and total walking, and participants reported that being able to see their improvement over time motivated them to continue their behaviours. The behavioural support call also encouraged monitoring of behaviour and reviewing of goals with participants describing a sense of accountability with the second call. Participants extensively discussed the app as the driving component of the intervention, supporting our previous reports of high engagement with Active 10 (16). The discussions revealed that another mechanism underlying behaviour change in this context was the ability of the app to increase motivation toward reward using gamification techniques (39). The performance of the desired behaviour (brisk walking) was reinforced by the positive feelings of encouragement and dedication resulting from these cups and trophies in the app.

Encouraging habit formation

The APPROACH intervention was informed by habit-theory (15), and the identification of habit formation as a mechanism of impact in both the qualitative interviews and questionnaire data demonstrate that this BCT was delivered effectively in the intervention. Participants reported that the leaflet, app, behavioural support call and planners all helped to establish sustainable walking habits. Gardner and colleagues define habit formation as "learning cue-behaviour associations, that when cued, automatically generate action impulses" (40). This sense of automaticity was described by participants in the qualitative interviews, whereby consistent repetition of their walking daily led to

enactment of brisk walking even during activities that previously wouldn't have involved this exercise intensity. These findings are also supported in the increased SRBAI results from baseline to follow-up, which showed an increase in initiation of walks, as well as the way walking was executed (i.e. briskly) (41). To reinforce the idea of habit, the walking planner cards were designed to promote habit formation, facilitate planning, and prompt participants to engage in PA (15, 40). However, both questionnaire data and interview data showed that the structured design of the planner cards were not compatible with the day-to-day changing schedules and lifestyles of some participants, highlighting the importance of conducting this process evaluation to account for and reconsider this contextual aspect of the intervention. The need for flexibility in lifestyle and planning was reported as a barrier by participants and further confirmed by the reflections of the intervention facilitator (CB) after discussing their use with participants.

Barriers to engagement: Cancer impact and competing commitments

Other contextual barriers included the impact of cancer and its treatment, having other competing commitments, technical difficulties with the app, and environmental influences. The side effects of cancer and its treatment have previously been identified as a key barrier to PA participation in systematic reviews (42), as well as our own preparatory work for this pilot RCT (13). Participants in this study reported that the impact of cancer and its treatment inhibited their ability to engage in some elements of the intervention due to different physiological, structural, and psychological factors. Cancer-related fatigue is the most reported symptom in people LWBC who have undergone treatment with prevalence estimates of up to 90% of those treated with radiotherapy and 80% of those treated with chemotherapy (43, 44). In this study, participants discussed fatigue symptoms and feeling that engaging with the intervention during treatment would have been difficult. Beyond this physiological barrier, the structural barrier of having any appointments for their cancer care also reduced their ability to engage with some components including the planner card, as there were many

hospital appointments that they had to attend and plan around. We have previously reported on the perceived suitability of timing of the APPROACH intervention, with most participants feeling that it was reasonable (16). While some participants felt that engaging during treatment would be difficult, others felt that it was useful to have something else to focus on and have control over (16). Involvement in PA at an earlier stage has also been associated with improved treatment response and tolerance, and quality of life (8, 45, 46). Taking this into account, the delivery of the APPROACH intervention during and after treatment for cancer is still endorsed, while recognising the contextual barriers such as this when interpreting APPROACH intervention outcomes.

Driving engagement: Support, trust and perceived benefits

Facilitators to engagement included having support from others, trust in healthcare professionals, the perceived usefulness of the intervention and perceived benefits of engagement with the intervention. The BCTs 'Social support (practical)' and 'Social support (emotional)' were competently delivered in line with the protocol (15, 25). Accordingly, participants recognised how having support from others such as family members and partners enhanced their engagement with the intervention, as well as feeling supported by the intervention facilitator. Social support has previously been identified as highly important in PA engagement (47), with reasons such as accountability being cited as helping to facilitate and promote engagement (48). In our preparatory work for this RCT, trust in healthcare professionals emerged as a crucial factor influencing engagement (13) and this was highlighted again in this study where incorporating an endorsed letter from the clinical care team enhanced app credibility.

Limitations

Limitations of this study include that only one intervention facilitator delivered all behavioural support calls which may explain the high fidelity ratings. It is crucial to consider the transferability of the intervention across individuals, particularly when envisioning integration into routine NHS

care (14, 16). Additionally, there may be some recall bias influencing results as most of the questionnaire data was collected at three-month follow up (49). Participants may have had difficulty in answering questions on earlier components (e.g., leaflet information) compared to components they were still using (e.g., app). Lastly, despite its recognition as a potential mechanism, it is difficult to assess the how the intervention helps to establish longer term habits which are key for PA maintenance (50), as this pilot RCT only examined outcomes at three months.

Conclusion

This study extends our previously published findings on the APPROACH pilot RCT (16) by demonstrating that the intervention was delivered as intended with high levels of engagement from participants. Additionally, this paper highlighted the potential mechanisms through which change occurs, such as habit formation and behavioural monitoring which are in line with the intended BCTs employed in this intervention. The process evaluation also highlighted important contextual factors to consider when progressing to the APPROACH main trial, including facilitators such as social support which played a significant role in promoting adherence to the intervention. The protocol for the definitive RCT will report on adaptions made to APPROACH based on the feedback gathered in this study. This process evaluation provides strong support for the progression to stage III definitive RCT to evaluate the effectiveness of the APPROACH intervention (began in November 2023) and enables a more nuanced understanding of how the APPROACH intervention works and the contextual factors to consider with implementation.

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Author Contributions

FK was responsible for conceptualisation, methodology, data collection and analysis, and drafting the manuscript. SS was responsible for conceptualisation, methodology, data collection and analysis, and drafting the manuscript. RB was responsible for conceptualisation and funding acquisition. CB was responsible for data collection and analysis. SW was responsible for conceptualisation, data collection and analysis, and methodology. CM was responsible for conceptualisation, data collection and analysis and methodology. PL (corresponding author) was responsible for conceptualisation, funding acquisition, data collection, and methodology. AF was responsible for conceptualisation and funding acquisition. All authors contributed to review and editing of the manuscript. PL and AF should be considered joint senior author.

Conflicts of interest

The authors report no conflicts of interest.

Abbreviations

BCT – Behavioural change technique

DBCI – Digital Behaviour Change Intervention

LWBC – Living with and beyond cancer

MRC - Medical Research Council

MVPA – Moderate-to-vigorous physical activity

NHS - National Health Service

PA – Physical Activity

RCT – Randomised controlled trial

SRBAI – Self-Report Behavioural Automaticity Index

UK – United Kingdom

WCRF - World Cancer Research Fund

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Supplementary Files

Multimedia Appendixes

Self Report Behavioural Automaticity Index (SRBAI).

URL: http://asset.jmir.pub/assets/89e1cadddd5c3b797b57a30eff8f1f98.docx

Exit Interview Guide.

URL: http://asset.jmir.pub/assets/273f2c8e244acdd571adb1c8846d2674.docx

Table S1 Adapted Dreyfus rating scale for the intervention BCT calls.

URL: http://asset.jmir.pub/assets/10e474549b6bc761d40ad5948be28ea4.docx

Supplementary Table S2. APPROACH intervention call behaviour change technique (BCT) checklist, intended delivery technique and mean delivery fidelity score.

URL: http://asset.jmir.pub/assets/d525399c87da099cae0960fb6e11a728.docx