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The feasibility and acceptability of randomising and delivering self-selected reminder schedules: The eRemind pilot randomised controlled trial

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TITLE PAGE

The feasibility and acceptability of randomising and delivering self-selected reminder schedules: The eRemind pilot randomised controlled trial

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ABSTRACT

Background

Digital health interventions to change health behaviours frequently use reminders, yet the most effective timing and frequency of delivery is unknown. Self-selected reminder schedules may facilitate behaviour change and are particularly relevant for the emerging field of adaptive interventions. This pilot examined the feasibility and acceptability of randomising and delivering self-selected reminder schedules to complete post-surgical physiotherapy exercises to inform future digital and adaptive interventions.

Methods

This pilot RCT was nested within a larger trial of a digital health intervention to support recovery from breast cancer surgery. Nested trial participants were re-randomised to either select their own reminder schedule (intervention) or to receive a pre-determined schedule (control). Feasibility outcomes were assessed using automatically collected data from the trial management system and included the proportion of participants who: were successfully re-randomised; selected their own reminder schedule; received reminders according to their selection; and recorded their exercises in the online log (as well as the number of times the log was accessed). Acceptability of the reminder schedule was assessed via an online survey. Descriptive analyses were conducted and outcomes compared to pre-specified targets.

Results

All eleven participants were successfully re-randomised (100%). Most intervention participants (57%) selected their own reminder schedule. Across both groups, 73% received reminders as intended, and 54% accessed the exercise log at least once, recording an average of 2.5 entries over the 3-week intervention period. As such 4 of the 5 pre-specified feasibility targets were not met. Most participants (63%) considered their reminder schedule to be acceptable.

Conclusion

Participants within an existing RCT were successfully re-randomised to self-selected or pre-determined reminder schedules. Although several pre-specified feasibility targets were not met due to technical delivery problems and limited engagement with the exercise log among control participants, these issues appear modifiable. Findings support refinement of the reminder delivery system before evaluation in larger feasibility and optimisation trials.

Trial registration

The parent trial (in which this study was nested) was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000417583). The nested trial was prospectively registered (4th July 2024) on the Open Science Framework (registration DOI: 10.17605/OSF.IO/R49PD).

Keywords

Digital health interventions; Tailored reminders; Behaviour change; reminder schedules; re-randomisation; REDCap interventions

Key messages regarding feasibility

- Uncertainties: Prior to this pilot, it was unclear whether patients within an existing RCT could be successfully re-randomised within REDCap to receive self-selected vs default reminder schedules. Furthermore, it was unclear whether they would choose a personalised reminder schedule when given the option, whether the personalised reminder schedules could be delivered accurately within the REDCap system, and whether participants would engage with an online exercise log sufficiently to support future digital and adaptive interventions.

- Key feasibility findings: All participants were successfully re-randomised (100%), demonstrating the feasibility of nested randomisation procedures within REDCap. However, only 57% of intervention participants selected their own reminder schedule, 73% of participants received reminders according to schedule, 54% accessed the exercise log, and did so an average of 2.5 times. Overall, four of the five pre-specified feasibility criteria were not met, largely due to technical delivery issues and low engagement with the exercise log.
- Implications: The findings support the feasibility of embedding additional randomisation procedures within an existing digital health trial but indicate that modifications are required before a larger study. These include providing participants with multiple opportunities to select and modify reminder schedules, strengthening quality assurance procedures, and using more objective and simpler methods of collecting adherence data rather than relying solely on an online exercise log.

BACKGROUND

Digital reminders, delivered via SMS, email or in-app notifications, are common features of Digital Health Interventions (DHIs).*(1)* Reminders are used to prompt a response from the receiver, which could include performing a target behaviour or providing information about the target behaviour. There is strong evidence that reminders are effective in supporting behaviour change*(2)* for a broad range of health outcomes, including physical activity, diet, smoking cessation, medication adherence, appointment attendance, vaccinations, cancer screening and mental health management.(3–11) However, less is known about the specific characteristics of reminders that maximise the likelihood of the intended response.

Tailoring reminders can enhance their impact. There are many forms of tailoring, including customising message content, greetings, language and mode of delivery.(12) Adjusting the reminder delivery schedule (i.e. timing and frequency) is also a simple and highly actionable tailoring strategy. Although DHI users report value in having control over when they receive reminders,(13) the most effective timing and frequency of reminders is unknown.(14) While several trials in a meta-analysis of digital health promotion interventions examined the effects of different reminder schedules within DHIs(15) only three of the 19 studies offered participants the opportunity to self-select their schedule,*(16–18)* and no study directly compared self-selected with pre-determined reminders. As such, further research is needed to determine whether self-selected reminder schedules are feasible, acceptable and associated with improved participant engagement compared with pre-determined schedules.

Furthermore, the timing and frequency of digital reminders have substantial implications for interventions such as Just-In-Time Adaptive Interventions (JITAIs) that depend on real-time participant interaction. Given the large numbers of DHIs, both existing and in development

that incorporate reminders and the rapid increase of JITAIs, evidence-based reminder schedules have enormous potential for wide-scale health impact.(14)

METHODS

Study aims

This pilot aimed to evaluate the feasibility and acceptability of randomising and delivering self-selected versus pre-determined reminder schedules for post-operative physiotherapy exercises for patients recovering from breast cancer surgery. A secondary aim was to explore exercise adherence outcomes as preliminary signals to inform the design of future trials of tailored reminder schedules.

Study design

This pilot study utilised a two-arm parallel RCT design. The pilot RCT was nested within a larger parent trial evaluating the '*RecoverEsupport*' digital intervention.(19) *RecoverEsupport* uses evidence-based behaviour change techniques,(20) including reminders, to encourage adherence to Enhanced Recovery After Surgery (ERAS) guidelines after surgery among women undergoing breast cancer surgery. ERAS guidelines recommend patients regularly do physiotherapy post discharge, making it an ideal target for evaluating reminder schedules over a longer period.(19) The parent trial was prospectively registered (ACTRN12624000417583) and the protocol for the nested pilot was published on the Open Science Framework platform prior to commencement. The study is reported according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials (Appendix A).

Setting and participants

Participants (in both the parent and nested trials) were recruited from a large metropolitan cancer hospital in Newcastle, New South Wales, Australia. Recruitment took place between August 2024 and August 2025, with final follow-up data collected in September 2025.

Parent trial eligibility: Women with breast cancer were eligible for the parent trial if they: were 18/+ years of age; were undergoing mastectomy surgery, with or without reconstruction; had internet access; spoke English; and were free from cognitive and emotional impairment.

Nested trial eligibility**:** All participants from the parent trial who were randomised to receive the *RecoverEsupport* intervention were eligible to participate in the nested trial. There were no further eligibility criteria applied for the nested trial.

Randomisation, blinding and consent

All parent trial participants who received access to *RecoverEsupport* were automatically randomised a second time, in a 1:1 ratio, into either the nested intervention group (given the option to self-select the reminder schedule) or the nested control group (sent reminders according to a pre-determined schedule), using a random number generator programmed by an independent statistician and executed within REDCap.

Due to the nature of the intervention, formal participant blinding was not possible. Research staff were also unblinded. However, the intervention was delivered automatically and outcomes were based on automatically collected data and participant self-report. Ethical approval was obtained to conduct secondary randomisation into the nested conditions.

Additional participant consent was not required for the nested trial, as all trial components and the risk/burden to the participant remained unchanged.

Intervention

All participants received an email 5 days after surgery outlining the importance of regularly doing physiotherapy exercises (Appendix B).

Intervention group*:* For intervention participants only, this email also included a link to a two-item REDCap survey. First, participants were asked to nominate the specific days of the week on which they wished to receive the reminders (unless they selected "every day") and were encouraged to select at least 3 days per week. They were then asked what time of day they wished to receive the reminders on the chosen days (morning, evening, or both). Morning reminders were sent at 10 a.m. given evidence of high open rates at this time,(21) and evening reminders were sent at 6 p.m. to avoid typical working hours. Intervention participants could receive between one and 14 reminders per week. Intervention participants who did not select any options were assigned the control reminder schedule.

Nested Control group: Control participants received three reminders per week, according to a pre-determined schedule: 10am Monday, 6pm Wednesday, and 10am Saturday (selected to include a range of times and weekends and weekdays).

Reminder emails:

Reminders were sent over a 3-week period commencing 5 days following surgery date. All participants received identical reminder emails encouraging exercise completion and recording in an online log in REDCap. Reminder emails (Appendix C) included: a generic

motivational message; links to videos and factsheets within the RecoverEsupport online module; a link to the online log (Appendix D); and tailored feedback based on their log entries.

Primary Outcomes

Feasibility: The feasibility of randomising and delivering self-selected reminder schedules was assessed based on five predefined progression criteria. Progression criteria were specified prospectively on OSF. Following consultation with the study advisory group and prior to analysis the targets for successful re-randomisation (1.) and receiving reminders according to schedule (3.) were revised from 100% to 95% to reflect the potential for technical failures in digital intervention delivery systems. Both the original and revised targets are reported for transparency, and the revised targets did not alter interpretation of the findings.

The proportion of participants who:

1. Successfully re-randomised to the nested study conditions

   Target: ≥ 95% of participants successfully re-randomised into one of the nested pilot study conditions.

2. Selected their own reminder schedule (intervention arm only)

   Target: ≥ 75% of intervention participants selected a personalised reminder schedule

3. Received reminders according to their self-selected or allocated schedule

   Target: ≥ 95% of participants received the correct reminder schedule. (Participants were considered to have received reminders according to schedule if the number and timing of reminders delivered matched the allocated or selected schedule recorded in REDCap).

4. Accessed the online exercise log

   Target: ≥ 75% of participants accessed the exercise log at least once

5. Engaged with the exercise log across the intervention period.

   Target: accessed log ≥3 times (on average) during the intervention period. (Given the reminders were sent for 3 weeks, this equates to an average of 1 per week).

Acceptability: The acceptability of the reminder schedules was assessed using a self-reported 5-point Likert scale item: “The frequency of the alerts was acceptable” (Strongly disagree – Strongly agree). Responses of "agree" and "strongly agree" were combined and taken as an indication of acceptability.

Exploratory Secondary Outcome:

Exercise Adherence was assessed based on the number of physiotherapy exercise sessions completed, as measured two ways: 1) recorded in the online log, or 2) reported in the 1-month follow-up survey.

Data Collection

Data were collected from multiple sources: information entered into the REDCap trial management system; system-generated trace data; and participant-reported online surveys. REDCap automatically sent participants links to the online surveys at baseline (immediately after consent into the parent trial) and 1-month post-surgery (28 days following their recorded date of surgery). Non-responders received emailed reminders to complete the surveys 3 and 6 days following the initial invitation.

Demographic characteristics: Age, sex, marital status, employment and education were collected in the baseline survey using standardised questions from population health surveys,

Australian Bureau of Statistics (ABS) standard questions, or adapted from ABS standard classifications.(23) In instances where self-report survey data was missing, demographic data were extracted from the inpatient medical record.

Clinical information: Clinical information (i.e., date and type of surgery) was obtained from the medical record and entered in REDCap by the Breast Care nurses.

Feasibility data: Feasibility outcomes were assessed using objective trace data (i.e. information automatically captured by REDCap) such as when and how often reminders were sent, as well as data that participants entered directly into REDCap (i.e. log entries).

Acceptability data: The question about the acceptability of the frequency of reminders was included in the 1-month post-surgery survey.

Analysis and sample size

Descriptive statistics on participant characteristics are provided. Outcomes are summarised descriptively, frequencies and percentages for feasibility and acceptability outcomes and means, standard deviations and ranges for secondary exercise adherence outcomes. Feasibility outcomes were then compared against the prespecified targets. Given the acceptability and feasibility objectives of the study, the sample size was not based on statistical power to detect intervention effects. Instead, a target of 30 participants was selected as a pragmatic sample to assess the feasibility and acceptability of trial procedures, identify any major implementation issues, and provide preliminary data to inform the design of a future definitive trial.(24)

RESULTS

There were eleven intervention participants in the parent trial, and all were included in the nested trial. The parent trial ceased recruitment before reaching its target sample due to

funding timelines, and consequently the nested trial also concluded prior to reaching its planned sample size. Seven participants were randomised into the self-selected reminder schedule and four to the pre-determined reminder schedule. REDCap data and system trace data were available for all participants. Six intervention participants (86%) and two control participants (50%) completed the 1-month survey. The progression of participants through this nested trial is shown in the CONSORT flow diagram (Figure 1).

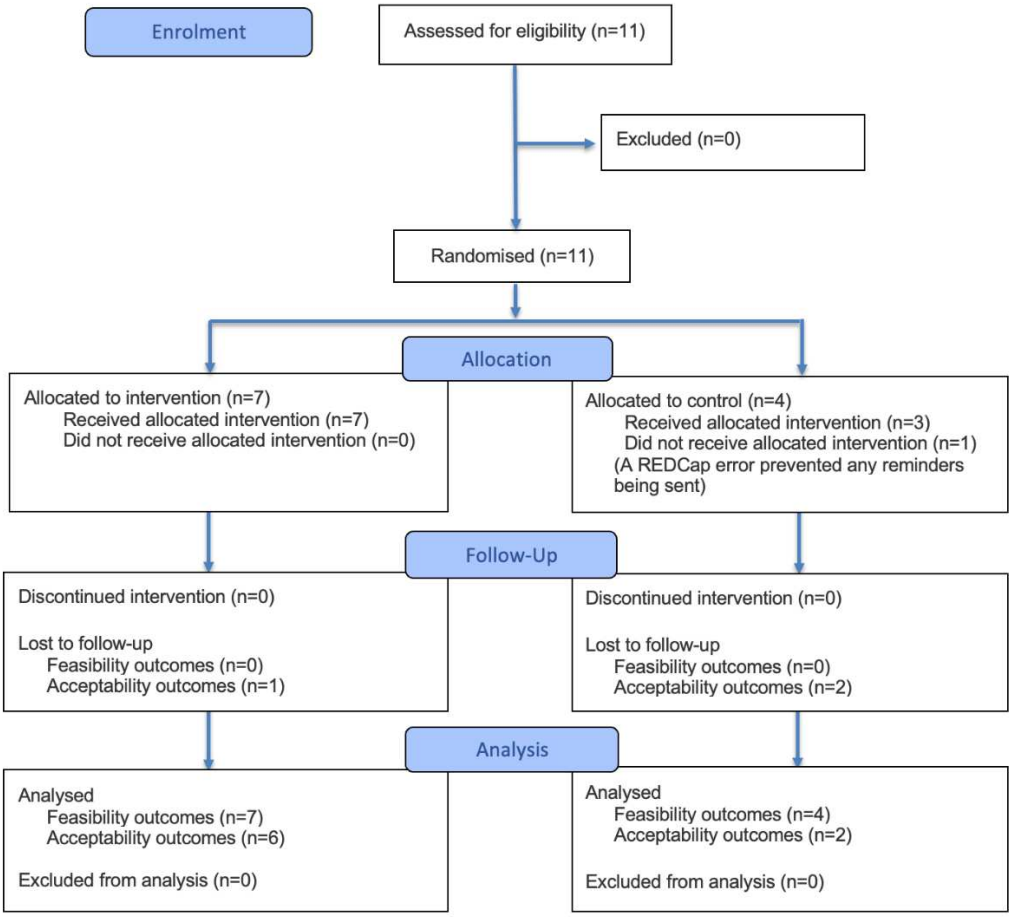


Figure 1.

Flow diagram of participant progression through the nested eRemind trial.

Trial Participants:

Participant characteristics at baseline are reported in Table 1. All participants were female, and the mean age was 57 years (range: 29-78 years). Most were married or living with a

partner (73%). Approximately half (n=6) reported having a trade or vocation as their highest level of education, with the remainder (n=5) having year 10/School Certificate or lower. Almost half (n=5) were currently employed. Control participants were, on average, approximately 15 years older than intervention participants. There also appeared to be differences in employment status between groups, with higher employment among intervention participants. No formal statistical comparisons of baseline characteristics were performed.

Table 1. Participant Demographics

Participant characteristics	Intervention (n=7)	Control (n=4)	Total (n=11)
Mean age in years (SD)	48 (15)	63 (15)	53 (16)
(range)	29 - 68	44 - 78	29 - 78
Marital Status			
Married or living with partner	5 (71%)	3 (75%)	8 (73%)
Single (widowed, divorced or separated)	2 (29%)	1 (25%)	3 (27%)
Education			
Trade or vocation training	4 (57%)	2 (50%)	6 (55%)
Year 10/School certificate or lower	3 (43%)	2 (50%)	5 (45%)
Currently employed	4 (57%)	1 (25%)	5 (45%)
Surgery type			
Mastectomy & delayed reconstruction	3 (43%)	2 (50%)	5 (45%)
Mastectomy & immediate reconstruction	2 (29%)	1 (25%)	3 (27%)
Mastectomy & no reconstruction	2 (29%)	1 (25%)	3 (27%)

Feasibility Outcomes

Feasibility outcomes are reported in Table 2.

Table 2. The feasibility and acceptability of randomising and delivering self-selected (intervention) vs pre-determined (control) reminder schedules

FEASIBILITY	Intervention (N=7)	Control (N=4)	Total (N=11)
Successfully re-randomised *Target: 95%**	7 (100%)	4 (100%)	11 (100%)
Selected own reminder schedule *Target: 75%*	4 (57%)	NA	NA
Received reminders according to schedule *Target: 95%**	5 (71%)	3 (75%)	8 (73%)
Accessed exercise log at least once *Target: 75%*	6 (86%)	0 (0%)	6 (54%)
Engaged with log across intervention period: # of times (range) *Target: ≥3 times*	4 (0-17)	0 (0-0)	2.5 (0-17)
ACCEPTABILITY	**Intervention (N=6)**	**Control (N=2)**	**Total (N=8)**
Strongly/Agreed that their reminder schedule was acceptable	4 (67%)	1 (50%)	5 (63%)
EXERCISE ADHERENCE (SECONDARY OUTCOMES)	**Intervention (N=7)**	**Control (N=4)**	**Total (N=11)**

	Mean (range)	Mean (range)	Mean (range)
Number of logged exercise sessions (recorded in the Exercise Log)	19 (0-27)	0 (0-0)	12 (0-27)
Number of self-reported exercise sessions (reported at 1-month follow-up)	18 (10-28)	11 (8-14)	16 (8-28)

*The prospectively posted targets for successful re-randomisation and reminder delivery were 100%. Prior to analysis, these targets were revised to 95% following advice from the study advisory group regarding the potential for technical failures in digital intervention delivery systems.

Successfully re-randomised: All participants (100%) were successfully re-randomised into the nested study conditions, meeting the pre-specified feasibility target of ≥95%.

Selected their own reminder schedule (Intervention group only): Although more than half of the intervention participants (n=4, 57%) selected their own reminder schedule, this did not meet the pre-specified feasibility target of ≥75%. Among those who did choose their own schedule, most (n=3, 75%) chose a schedule that exceeded the frequency of the pre-determined reminder schedule of three per week. The remaining three participants did not select their own reminder schedule and received the pre-determined schedule.

Received reminders according to schedule: Overall, 73% of participants received reminders in accordance with their set schedule, which was less than the pre-specified feasibility target of ≥95%. Most of the intervention participants (71%) received reminders according to their chosen schedule. Of those who did select their own schedule (n=4), only half of the participants (n=2) received the schedule according to what they had chosen. A system error meant that two intervention participants (both of whom had self-selected their own schedule) received an incorrect number of reminders; one was not sent two reminders, while the other

309 received eight additional reminders. All three intervention participants who did not select a
310 reminder schedule correctly received reminders according to the pre-determined schedule.
311 Three of the four control participants (75%) received their pre-determined reminder schedule
312 correctly, with one control participant receiving no reminders at all due to an error with an
313 external REDCap module.
314
315 *Accessed the online exercise log:* 86% of intervention participants accessed the exercise log
316 at least once, whereas 0% of participants in the control group accessed the exercise log. As
317 such, the overall proportion of participants (54%) who accessed the log was lower than the
318 pre-specified target (75%*)*.
319
320 *Engaged with the online exercise log*: intervention participants accessed the exercise log an
321 average of 4 times (range 0-17 times), whereas control participants did not access the
322 exercise log at all. Across both groups, participants accessed the log a mean of 2.5 times,
323 which was below the pre-specified target of ≥3 times accessed. Overall, one of the five pre-
324 specified feasibility criteria was met (the proportion of participants successfully re-
325 randomised).
326
327 **Acceptability Outcome**
328 *Strongly/Agreed that their reminder schedule was acceptable:* Within the intervention group,
329 4 of the 6 participants (67%) who completed the 1-month survey 'strongly agreed' that the
330 reminder schedule was acceptable. Of those, one (25%) had not chosen a schedule and
331 received the pre-determined schedule. One participant reported a neutral response, and one
332 participant, who opted to receive the maximum number (43) of reminders, disagreed that the
333 reminder schedule was acceptable. Within the two control group participants who completed

the 1-month survey, one 'strongly agreed' (50%) that the reminder schedule was acceptable and the other reported a neutral response.

Secondary Exercise Adherence Outcomes

Number of logged exercise sessions: Within the online log, intervention participants recorded a mean number of 19 exercise sessions (range 0-27), whereas control participants recorded no sessions (as no control participant accessed the log).

Number of self-reported exercise sessions completed: In the 1-month survey, intervention participants reported a mean of 18 exercise sessions (range 10-28), while control participants reported a mean of 11 exercise sessions (range 8-14).

Fidelity and quality assurance

A research assistant monitored the REDCap email log to ensure emails were being sent in accordance with the correct schedule. During this process it was discovered that a REDCap error meant that some reminders to controls participants (6/10) had omitted a diagram showing an alternative way to access the log. However, all reminders to all participants contained the link to access the log.

DISCUSSION

This nested pilot study provides useful evidence to inform future trials of self-selected digital reminders. The findings relating to feasibility were mixed. It was feasible to re-randomise participants within an existing 'parent' RCT with all participants successfully randomised, exceeding the target (100% vs 95%). When given the option, most intervention participants chose their own reminder schedule although this was less than anticipated (57% vs 75%). System errors meant that not all reminders were correctly sent out, and as such, this indicator

of fidelity fell below the target (73% vs 95%). Furthermore, although intervention participants used the log to record their physio exercises, engagement with the log among control participants was negligible (86% vs 0% of participants accessing it, and logging on an average of 4 vs 0 times), and as such the targets were not met. Overall, four of the five pre-specified feasibility targets were not met. Low engagement with the exercise log, particularly among control participants, contributed to two feasibility targets not being achieved.

These findings have implications for the use of self-selected reminder schedules in future trials of digital and adaptive interventions. Participants allocated to the self-selected reminder condition recorded more exercise sessions (in the online log) and reported higher exercise adherence (in the 1-month follow-up survey) than control participants. As these exploratory outcomes were assessed in a small pilot study not powered to evaluate effectiveness, these findings should be interpreted cautiously. If the observed differences in exercise adherence are replicated in future studies, potential explanatory mechanisms may include enhanced autonomy, accountability or intention to act associated with participant choice, or through alignment to their preferences.(25) (26)

The low levels of engagement with the online log, and the differences in self-reported exercise sessions vs the number of sessions recorded in the log, suggest that this format alone is not a sufficient way of collecting information about this type of behaviour change (exercise adherence), and other ways of collecting this information should be incorporated. Simplifying this data collection process may help, e.g. rather than clicking on a link and being taken to REDCap to enter the data, having participants directly reply to an SMS or involving more objective data collection such accelerometers and smartwatches could be employed.

Fewer participants than anticipated opted to choose their own reminder schedule. This may be a result of the timing of the choice, that is, a few days after their cancer surgery; a time when patients are exhausted and focused on short term symptom management. Furthermore, participants only had one opportunity to choose their reminder schedule, and received no follow-up prompts to make their selection. Increasing the number of opportunities to make a selection may have increased the proportion of participants selecting their preferred schedule and it is recommended that future interventions incorporate this feature. It is notable that most participants in this nested pilot who chose their own schedule opted for more frequent reminders (on average eight reminders per week) compared with the pre-determined schedule (three reminders per week), and that acceptability was commonly reported within this group. This finding suggests that participant preferences may be an important consideration in the design of future adaptive interventions, including JITAIs. The only intervention participant who reported the reminder schedule as unacceptable had chosen the maximum number of reminders offered (43), again reinforcing the importance of allowing participants to modify their preferences throughout the intervention. It is also recommended that future trials employ comprehensive fidelity checks encompassing all aspects of the trial and intervention.(27) This will ensure that system errors, not uncommon when using digital delivery systems, are identified and fixed early, thus affecting as few participants as possible.

A key strength of this pilot is that it collected novel data about the feasibility and acceptability of self-selected digital reminder schedules to inform the development of future trials of digital and adaptive interventions. It pre-specified and prospectively registered key indicators and targets. Furthermore, it was conducted within a larger RCT, with patients actively having breast cancer treatment. This allowed us to pilot the intervention under comparable conditions to which it would subsequently be tested. As a result, the challenges

identified are directly relevant to the design of future trials of self-selected reminders. This is particularly important given the under-representation of clinical populations within these types of trials. Another strength of this study is its use of REDCap, a free purpose-built system for both intervention delivery and data collection, enabling the study to be easily and inexpensively replicated. In addition, the study incorporates both objective trace data and self-reported outcome data, reducing the potential for bias.

The main study limitation is the small sample size, largely attributable to recruitment challenges within the parent trial. This means that it is difficult to capture wide diversity across participants, which also may limit the generalisability of the findings. Given the low numbers, it is unsurprising that an imbalance in age between the intervention and control groups was observed. The digital nature of the intervention means that it is possible that age may have influenced engagement with the digital reminders. However, a recent large Australian study found that digital technology use is still very high in older adults up to 75 years.(28) Stratifying randomisation by age in future trials may help mitigate this potential source of bias. Additionally, despite having access to a REDCap programmer, technical errors occurred due to both human and system errors. While such issues are likely to have less of an impact in larger and longer trials as early quality checks identify and correct errors (and systems stabilise), they had a disproportional impact in this small and short pilot, reinforcing the need for thorough pre-trial testing. Furthermore, acceptability findings with respect to the control groups should be interpreted cautiously due to the low completion rate. Finally, reminders were delivered via email only and engagement may have differed had reminders been sent via SMS or if participants had been able to choose their preferred delivery method (email or SMS). However, a 2022 study comparing SMS and email reminders as part of a DHI found no significant difference between the two modes of delivery

in terms of program adherence.(29) Lastly, while the number of times the exercise log was accessed and the number of entries within it were examined, these metrics may not fully capture adherence to prescribed exercise frequency. More detailed measures (e.g., daily logging consistency or proportion of days with recorded exercises) and more objective measures of exercise adherence should be considered in future interventions and trials.

CONCLUSION:

This small, nested pilot study demonstrated that participants could be successfully re-randomised within an existing RCT to self-selected or pre-determined reminder schedules. Several pre-specified feasibility targets were not achieved due to technical delivery issues and limited engagement with the exercise log. Nevertheless, participant uptake of self-selected reminders and generally favourable acceptability ratings suggest that this approach warrants further refinement and evaluation in larger feasibility and optimisation studies.

ABBREVIATIONS:

SMS - Short Message Service

DHI - Digital Health Intervention

JITAI - Just-In-Time Adaptive Intervention

RCT - Randomised Controlled Trial

ERAS - Enhanced Recovery After Surgery

ACTRN - Australian New Zealand Clinical Trials Registry Number

CONSORT - Consolidated Standards of Reporting Trials

REDCap - Research Electronic Data Capture

OSF - Open Science Framework

ABS - Australian Bureau of Statistics

SD - Standard Deviation

DECLARATIONS

Ethics approval and consent to participate

The study received approval from the Hunter New England Local Health District Human Research Ethics Committee (2022/ETH02010), the University of Newcastle (H-2023-0298) and the Calvary Mater Newcastle (2022/STE03757). All participants consented to trial participation.

Consent for publication

Not applicable

Availability of data and materials

Data and materials are available from the authors upon reasonable request and pending ethics approval.

Competing interests

The authors have no competing interests.

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485 in study design, data collection, analysis and interpretation of data, or the writing of this
486 manuscript.
487

488 **Authors' contributions**

489 EF led the development and writing of this manuscript and RW, KC, KS and ES secured the
490 funding for the trial. RW, EF, ES and APP developed the intervention and all authors
491 contributed to the development and implementation of trial methods. All authors contributed
492 to the analyses and interpretation. All authors contributed to manuscript drafting and
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498

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