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A supportive text message intervention for individuals living with endometriosis (EndoSMS): Randomized controlled pilot and feasibility trial

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ABSTRACT

Introduction: As a high symptom burden chronic condition, endometriosis is associated with diminished quality of life (QoL) and psychological distress. The EndoSMS text message intervention was developed to inform and support individuals living with endometriosis. The primary aim of this study is to assess the acceptability, feasibility and preliminary efficacy of EndoSMS, to improve endometriosis-specific QoL and reduce psychological distress in a randomised controlled trial, compared with care as usual. We will additionally assess the impact of EndoSMS on self-efficacy for managing endometriosis.

Methodology: A two-arm parallel pilot randomised controlled trial with waitlist control was conducted. Baseline assessments included QoL, psychological distress, self-efficacy, demographic and medical variables. Following baseline survey completion, participants were randomised to either the Intervention (EndoSMS: 3-months of text messaging) or Control condition. At 3-month follow-up, all participants completed an online survey reassessing outcomes, and Intervention participants provided quantitative and qualitative user feedback on EndoSMS.

Results: Data collection commenced on 18 November 2021 and was completed on 30 March 2022. Descriptive statistics will be used to analyse feasibility and acceptability of the intervention. Preliminary efficacy analyses will be conducted using linear mixed models for QoL, psychological distress and self-efficacy outcomes. Subgroup analyses will also be conducted for typically underserved populations (e.g., rural/regional).

Conclusion: This pilot will provide acceptability, feasibility and preliminary efficacy evidence for the impact of a supportive text messaging program for endometriosis. It will contribute to understanding how to optimally support individuals in living with and managing their endometriosis.

Trial Registration: Australian New Zealand Clinical Trials Registry.

1. Introduction

Endometriosis is a highly prevalent, incurable and painful chronic condition affecting 1 in 9 Australians [1] and 10% of biological females globally [2]. Symptoms include chronic pelvic pain, dyspareunia, altered bladder and bowel function, abdominal bloating and infertility [3]. Despite the chronic symptom burden [4], interaction with medical professionals is sporadic [5]. This contributes to individuals having limited understanding of their illness, and feeling misunderstood by health professionals [6] and not supported [7]. Endometriosis is characterised by poor quality of life (QoL) [8], a high prevalence of psychological distress (e.g., depression, anxiety, stress) [9,10], and impairments in social functioning [11]. Issues with low self-image [8], low self-esteem [12] and lack of self-compassion [13] further contribute

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to psychological distress. Clearly psychologically supportive interventions are warranted for individuals living with endometriosis. The delivery of simple, easy-to-implement strategies for improving quality of life and emotional wellbeing (e.g., advice for self-care), and providing information and guidance for managing endometriosis (e.g., tips on how to reach out for support), may prove effective for individuals living with endometriosis.

One promising low-cost approach to providing readily accessible, supportive interventions in medical settings is via mobile phones [14] (i.e., mHealth). Access to mobile phones worldwide is ubiquitous, with 90% of the global population (including Australians) having ready access to a mobile phone [15], providing direct internet access [16]. mHealth has been used with women with chronic pelvic pain to deliver mindfulness meditation through an mobile phone-based application [17]. However, users of this phone application expressed a number of concerns navigating and using this technology (e.g., internet connectivity issues, limited storage space) [17]. Text messaging is another type of mHealth intervention which is highly accessible, not requiring internet connection or navigation of a new phone application [18]. Text messaging provides a scalable, easy-to-implement approach to rapidly disseminating curated health information and resources to individuals in between usual clinic visits and for those whose clinic access is challenged by geographic isolation or COVID-19 related public health measures [19]. A further benefit is that texts require little effort on the part of the recipient and can be read at a time of convenience [20].

A mixed methods needs analysis study with individuals living with endometriosis revealed a strong desire for easy-to-access, reliable and supportive information [21]. Reflecting the high prevalence of psychological distress, there was an expressed desire for psychological and emotional support, particularly regarding self-compassion and social relationships [21], consistent with prior research [13]. Consequently, we developed EndoSMS, a supportive text messaging intervention [21] using co-design with individuals living with endometriosis, clinical health professionals and researchers [21], to ensure the relevancy and suitability of the resultant intervention [22,23]. Designed for delivery over a 6-month period, EndoSMS comprises 371 text messages for one-way, automated delivery across several domains providing general information about endometriosis and tips, strategies and guidance for promoting psychological wellbeing [21]. Four messages are delivered per week, an optimal delivery schedule identified in prior text message interventions [14,24]. These text messages have demonstrated high acceptability, relevance and readability from both individuals with endometriosis and healthcare professionals [21], consistent with prior text message intervention research [14,20]. Addressing key challenges for individuals living with endometriosis, EndoSMS aims to improve psychosocial aspects of wellbeing as reflected in QoL and emotional health.

To date, no study has examined the use of an endometriosis-specific mHealth intervention or a text message intervention in this context. Text-based interventions generally have improved aspects of psychological wellbeing, such as QoL [26], patient empowerment [27], perceived support [28] and self-efficacy for chronic condition management [29]. Two text messaging interventions providing information and psychologically supportive messaging (Text4Hope over 3 months addressing mental health concerns during the COVID-19 pandemic [30]; Text4Support providing cognitive-behavior based text messaging over 6 months to support community-based adults with addiction and mental health concerns [31]) similar to EndoSMS, are of particular relevance to the endometriosis context as both primarily target a female audience. Single arm feasibility studies of these two interventions indicate high user acceptability and potential improvements in mental wellbeing (i.e., loneliness, stress, QoL [31], psychological distress) [30]. Notwithstanding high dropout rates (95.5% [30]; 89.3% [31]) and the lack of a randomised controlled design, these preliminary findings suggest that supportive text-message interventions may be acceptable and useful for individuals living with endometriosis, a population facing ongoing challenges in terms of psychosocial wellbeing, medication adherence and self-management [8,32].

1.1. The current study

Building on our prior work in cardiac [20] and breast cancer contexts [14], and the initial demonstrated acceptability of the EndoSMS text messages [21], this paper details the protocol of a randomized control pilot study to investigate the acceptability, feasibility and preliminary efficacy [33] of a brief (3-month) version of the EndoSMS intervention. This brief version is expected to show evidence of indicative benefit (i.e., preliminary efficacy) for improved QoL, diminished psychological distress and enhanced management of the self-regulatory aspects of living with endometriosis [34].

2. Methods

2.1. Design

This pilot study is an exploratory two-arm parallel randomised controlled trial (RCT) with waitlist control (see Fig. 1). A waitlist control with usual-care was deemed the most ethical choice for control, as it allows for the testing of experimental effects and provides all participants the opportunity to benefit from the intervention [35]. After baseline survey completion, participants were randomised in a uniform 1:1 allocation ratio to the Intervention (brief 3-month EndoSMS) and Control (waitlist) condition, using an online central randomization program (randomizer.org). Generation of the allocation sequence was conducted by the lead investigator (KS), with participants allocated by the research assistant (MP). Due to the behavioral nature of this trial, no blinding took place. Participants were told the aim of the study was to understand the impact of a text messaging program designed to support individuals with endometriosis. This research followed Enhancing the QUAlity and Transparency Of health Research (EQUATOR) recommendations regarding the conduct of health research [36]. This protocol adheres to SPIRIT guidelines for clinical trial protocols (see Supplementary File 1) [37]. The trial is registered with the Australian New Zealand Clinical Trials Registry (#ACTRN12621001642875) and CONSORT guidelines were followed for the conduct and reporting of the pilot [38].

2.1.1. Participants

Participants were recruited from the Australian-based online community organisation Endometriosis Australia. Participants who self-reported being: (1) at least 18 years old; (2) clinically diagnosed with endometriosis; (3) located in Australia; (4) with access to a mobile phone and the internet; and, (4) able to read and complete surveys in English were invited to participate. Data collection commenced on 18 November 2021 and was completed on 30 March 2022.

2.1.2. Procedure

Recruitment material shared on social media by Endometriosis Australia contained a link to the study consent form and online survey (see Supplementary File 2) on the Macquarie University REDCap system. Individuals providing online informed consent and meeting eligibility criteria were invited to provide contact details (including their nominated mobile phone number) and then commence the online baseline survey (see Fig. 1) including measures of sociodemographic, medical (including whether they have difficulty remembering to take prescribed medication for endometriosis) and psychological variables. Preferred time to receive a text message was also measured at baseline (i.e., morning, daytime, evening).

All participants completing at least 70% of the baseline survey were randomized to either the Intervention (EndoSMS messaging for 3-months) or Control (waitlist care as usual) condition. Within 48 h of baseline survey completion, participants were notified of their

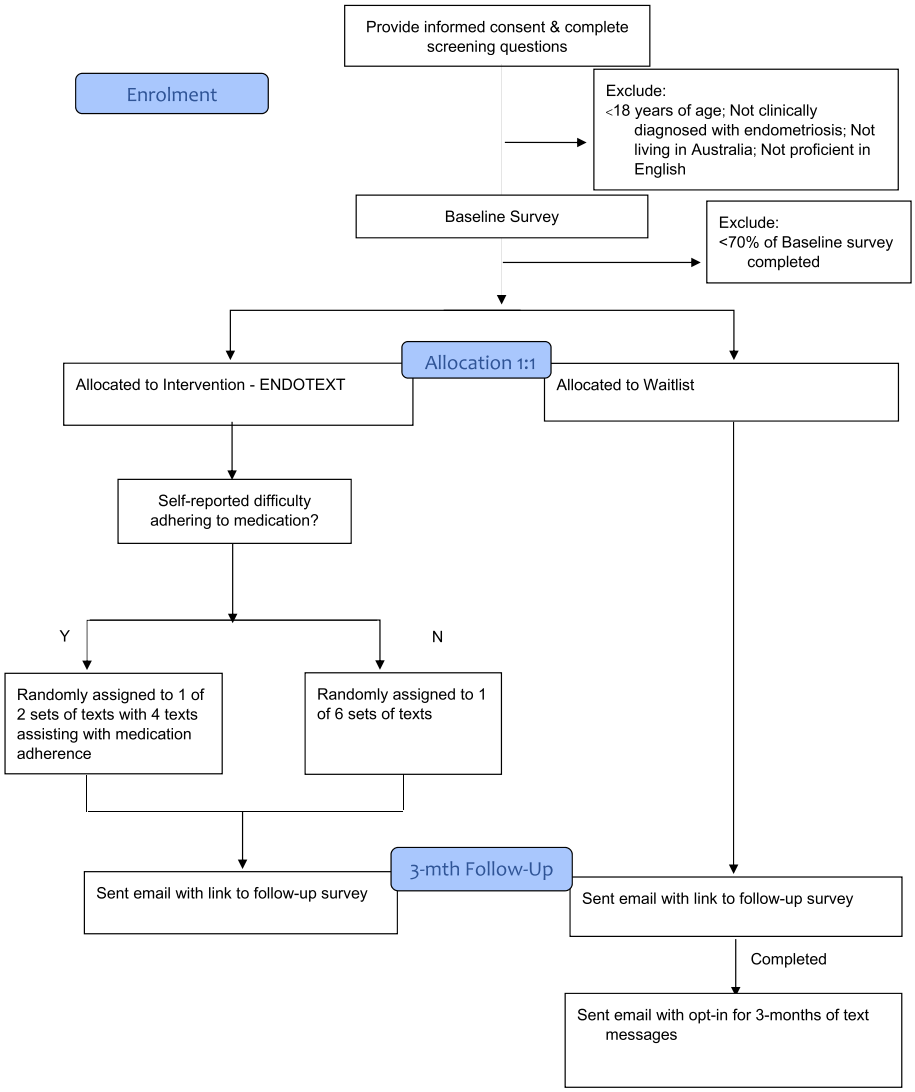

Fig. 1. Flow of participants through the study.

assignment: Intervention participants then started receiving the text messages and Control participants were informed they can opt-in to receive the text messages after the 3-month survey completion.

Three months later, participants were sent an email containing a link to the online follow-up survey re-assessing outcome variables. Additionally, Intervention participants were asked to provide quantitative and qualitative feedback on their user experience with EndoSMS. After completing the follow-up survey, Waitlist participants were invited via email to opt-in to receive EndoSMS for a period of 3-months. Non-responding participants for the follow-up survey received three reminders via email (one week late), text message (2 weeks' late), and phone call (2+ weeks late) requesting them to complete the survey. Ethics approval was granted from the Macquarie University Human Research Ethics Committee (#52021963527729).

2.1.3. Intervention

EndoSMS is designed to provide supportive text messages to individuals living with endometriosis [21]. Messaging covers a range of domains including: general endometriosis information; physical health; emotional health; looking after and caring for your body; social support, patient empowerment; and, interpersonal issues. For this feasibility study, participants received four semi-personalised text messages (to their preferred name) delivered to their nominated mobile phone number each week for three months, free of charge. Each text message has a maximum of 160 characters and should take less than 1 min to read. EndoSMS was developed using an established mixed-methods process [39], including consumers and a research-trained citizen collaborator as co-designers. The detailed development process is reported separately [21]. Briefly, the intervention content and format was derived from the preferences expressed in focus groups and surveys, conducted with individuals with endometriosis, and relevant health professionals and researchers.

To ensure all 371 developed text messages are evaluated, Intervention participants received one of eight sets of 48 unique text messages (i.e., four messages per week over 12 weeks) containing a random assortment of different text message themes. In two subsets, four text messages from the general bank were replaced by four messages designed to assist individuals in taking prescription medication. These two subsets were randomly assigned to Intervention participants who indicated difficulties remembering to take medication. All other Intervention participants were randomly assigned to one of the six remaining text message sets. Participants who nominated a preferred time of day (i.e., morning 9–12pm, daytime 9-5pm, night-time 5–9pm) were allocated their text messages accordingly. Participants not providing a time preference were defaulted to receive the daytime slot. Text messages were sent using an automated system.

2.1.4. Control

Waitlist participants received no additional support beyond their usual care (e.g., GP/gynaecologist appointments) up until the trial completion at 3-months, when they were given the opportunity to opt-in to receive the text messages for 3-months, free of charge.

2.2. Measures

2.2.1. Acceptability

Quantitative and qualitative measures were used to assess the suitability and perceived utility of the text messages and program structure, as well as whether participants liked or disliked any specific messages [14]. A series of 5-point Likert-type questions (e.g., "I found the messages useful") with response options ranging from "strongly disagree" (1) to "strongly agree" (5) was used to determine whether the intervention was acceptable, with an average score of 3 or more indicating adequate acceptability. Further information on the acceptability was assessed through additional questions (e.g., "The language of the text messages was appropriate") and optional open-text free-response questions (e.g., "What was your favourite message(s)?").

2.2.2. Feasibility

Feasibility was assessed based on recruitment and retention rates. Specifically, the number of participants visiting the survey site, consenting, completing baseline and post-intervention measures was examined. Attrition at any point (e.g., from visiting study cite to providing consent; from consent to baseline completion; from baseline to post-intervention) greater than 20% will be considered indicative of feasibility issues [40]. Further, delivery system usage data (e.g., number of undelivered text messages) will also be examined, along with any contact from participants.

2.2.3. Sociodemographic and medical data

At baseline, demographic (age, marital status, education level, employment status, residential location) and medical (method of diagnosis, diagnostic delay, fertility, endometriosis severity, treatments, symptoms) information was collected.

2.2.4. Preliminary efficacy measures

Assessment of the primary (QoL and emotional health) and secondary (self-efficacy) outcomes is described in Table 1.

2.2.5. Sample size

The aim of pilot studies is to provide indicative data of an intervention's potential benefit [45], hence this trial aimed to gain user acceptability, feasibility and preliminary efficacy data to inform a future definitive trial of the full-strength (i.e., 6-month) EndoSMS intervention. An a-priori power analysis using G*Power indicated a sample size of 265 participants was necessary to detect a small-to-moderate change in the primary outcome of EHP-30 emotional wellbeing, with three covariates. This was guided by the RCT results of a less psychologically focused, 6-month text message intervention conducted by the authors [46], which recorded a small change in quality of life post-intervention, in a different health population (breast cancer survivors). Hence, we recruited a sample (N = 274) of just over 265 participants, largely evenly distributed (139 Intervention, 135 Waitlist) across the conditions, to gain indicative data on the full intervention's potential benefit.

Table 1
Primary and secondary outcome measures [41–44].

Outcome	Instrument	Details
Endometriosis QoL, Primary	Endometriosis Health Profile Questionnaire-30 (EHP-30) [41]; contains five subscales: pain, control and powerlessness, social support, emotional wellbeing and self-image	30-items, 5-point Likert-type scale, score range: 0–100, higher scores indicate greater impairment in QoL.
Emotional health, Primary	Depression, Anxiety and Stress Scales 21 item (DASS-21) [42]; contains three subscales: Depression, Anxiety, Stress	21 items, 4-point Likert-type scale, score range: 0–21, higher scores indicate worse emotional health
Self-efficacy, Secondary	PROMIS Self-Efficacy for Managing Chronic Conditions Short-Form [43,44]; contains four subscales: managing symptoms, daily activities, managing medication/treatment and social interactions	4-item subscales, 5-point Likert-type scale, score range: 4–20, higher scores indicate greater self-efficacy.

3. Results

3.1. Analyses

Data will be de-identified prior to analysis and not traceable to any individuals. In this mixed methods study, quantitative analyses will be carried out using SPSS version 27 with an overall critical alpha of .05. Descriptive statistics (means and standard deviations for continuous variables; frequencies and percentages for categorical variables) will describe sample characteristics.

3.2. Feasibility

Descriptive statistics (frequencies and percentages) will be used to detail retention rates and SMS-system delivery data (e.g., number of sent messages vs. bounced messages).

3.3. Acceptability

For Intervention participants, quantitative feedback will be detailed using descriptive statistics (means, standard deviation). Qualitative participant feedback on EndoSMS will be thematically analysed [47] with at least two independent coders using a six-stage inductive template approach [48,49], including: familiarization with the data set, generation of initial codes, searching, refining and defining themes, and integrating results to construct a report.

3.4. Preliminary efficacy

Baseline differences between assigned groups and differences between study dropouts and completers will be assessed using one-way ANOVA (continuous variables) and chi-square test of independence (categorical variables). Linear mixed models with maximum likelihood estimation will be conducted to determine the impact of the brief text message intervention on primary and secondary outcomes at the 3-month timepoint, relative to wait-list controls. Group, time and group by time interactions will be examined for all outcomes, controlling for age, education and perceived endometriosis severity. Time by condition effects for primary outcomes will be interpreted using relevant established minimally clinically important differences (MCIDs) [50,51]. Four separate sub-group analyses will also be undertaken for participant identifying as: 1) being Indigenous; 2) taking hormone medication; 3) located in a rural/regional area; and 4) having medication taking difficulties, as each of these subgroups have increased risk of either being medically underserved [52,53] or experiencing adverse endometriosis-related impacts [54]. Lastly, sensitivity analyses, including only participants completing baseline and 3-months follow up assessments, will be conducted.

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4. Discussion

The EndoSMS pilot and feasibility trial will provide valuable insights

into the impact of a co-designed mHealth text message intervention developed specifically to meet the diverse needs of individuals with endometriosis [21]. These findings will extend the emerging evidence based demonstrating the feasibility [31] and efficacy of psychologically-focused text message interventions [26–31]. With a focus on providing psychologically-supportive messaging [21], we anticipate the greatest benefits derived from EndoSMS will be improvements in wellbeing as reflected by endometriosis-specific QoL and psychological distress. We further anticipate that the highly accessible EndoSMS intervention [21] may be particularly suited for individuals geographically isolated from specialist clinics (e.g., those living in regional/rural locations) [52–54] or for those experiencing other barriers to healthcare access (e.g., perceived stigma) [55,56]. Moreover, individuals taking hormone treatments for endometriosis tend to experience a number of side effects [54], which may impair QoL, and thus may respond more to a supportive intervention such as EndoSMS. Identifying the characteristics of users most likely to benefit from the EndoSMS intervention in this pilot and feasibility study, combined with open-ended program feedback, will help elucidate the barriers and enablers to widespread implementation of the text message program.

When considering this protocol, some risks and limitations need to be considered. A key limitation is that these data will only reflect a brief, shortened version of the EndoSMS intervention (i.e., 3-months of text messaging) contrary to the intended 6-month text message delivery and short-term outcomes. Clearly, future large-scale efficacy trials are needed to assess the full impact of the EndoSMS intervention delivered over a six month period, as intended. Further, the pilot study design precludes any possibility of controlling for differences in clinical care provided to study participants, a factor that may impact on our outcomes, particularly self-efficacy. Future large scale efficacy trials stratified by factors such as clinical care are needed to provide longer term efficacy data. As an mHealth intervention, by its very nature EndoSMS precludes access to those who are not mobile phone users; yet, with mobile phone use largely ubiquitous in young to middle-aged adults (the age groups most affected by endometriosis [8]), this risk is minimal. Since the cost of delivering the EndoSMS messages is supported by the funder of this research (Endometriosis Australia), there should be no financial barriers to participation in this study. Further, although SMS-system delivery analytics provide some indication of intervention adherence, it will not be possible to assess true drop-out from text message interventions, where participants may simply block the study number.

5. Conclusion

In summary, this simple, highly accessible text message program uses positive, informative and semi-personalised messages to support individuals living with endometriosis. This three-month pilot randomised trial will produce indicative feasibility and acceptability data for future clinical trials and implementation of this intervention and will extend the emerging evidence based demonstrating the feasibility [31] and efficacy of psychologically-focused text message interventions [26–31]. Importantly, user feedback from this pilot study will also help inform further improvements and refinements of the text message corpus for future research and eventual implementation of this intervention.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Funding for this project was granted by Endometriosis Australia. JR is funded by a NHMRC Investigator Grant Leadership Level 2 [GNT2007946]. AS receives a PhD stipend provided by the University of Sydney, Australian Government Research Training Program Scholarship and a Supplementary Postgraduate Research Scholarship in Breast Cancer.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101093.

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