HREA Project Description – ENDOTEXT

Version 1

Aim: Applying psychological and communication theory, this study will co-design and pilot a text message program (ENDOTEXT) to improve the mental and physical health of individuals living with endometriosis. Our multidisciplinary team with expertise in health psychology, public health, allied health, endometriosis management and surgical/clinical gynaecology will co-design a large bank of text messages with consumers, focused on providing information about endometriosis management, healthy lifestyle behaviours (e.g., diet, exercise) and mental health support. Following successful piloting of ENDOTEXT, we will collaborate with Endometriosis Australia to ensure that ENDOTEXT is available to the wider population of Australians living with endometriosis.

Project Team Roles & Responsibilities

* Lead Investigator - Professor Kerry Sherman (Health Psychologist, Macquarie University, Department of Psychology) has extensive experience in women’s health focusing on adjustment to chronic conditions and e-health interventions. She also has lived experience of endometriosis. Sherman is the lead investigator of ENDOTEXT and will be responsible for all aspects of the project.
* Co-Investigator - Professor Julie Redfern (Physiotherapist, Westmead Applied Research Centre (WARC), University of Sydney) has extensive experience in text messaging interventions improving health outcomes for people with chronic disease; she will inform all aspects of the project.
* Co-Investigator - Dr Mike Armour (Senior Research Fellow, Western Sydney University) researches women's health with a focus on endometriosis. CI Armour’s expertise will inform intervention development and dissemination.
* Co-Investigator - A/Professor Blake Dear (Director of MindSpot Clinic, Macquarie University) has extensively developed and evaluated e-health programs for chronic health conditions. He will inform all aspects of the project.
* Co-Investigator - Ms Anna Singleton (PhD Student and Research Associate, WARC) has developed (with JR, KS) a text messaging intervention for women after breast cancer. Her experience will inform all aspects of this project.
* Co-Investigator - Ms Tanya Duckworth is a woman with lived experience of endometriosis who is also trained in research. Her role as the research-trained citizen collaborator and a member of the Steering Committee will inform all aspects of the project.
* Assistant Investigator - Ms Donna Ciccia, Director of Endometriosis Australia and an individual with lived experience of endometriosis, will serve on the Steering Committee providing high-level advice and inform the intervention up-scaling strategy.
* Assistant Investigator - A/Professor Michael Cooper (Head of Gynaecology, Royal Prince Alfred Hospital) is an endometriosis surgeon/researcher providing a clinician’s voice to this project.
* Assistant Investigator - Kelly Ann Parry (Lecturer, Western Sydney University) is an educator/researcher in health and physical education will help design text messages.
* Assistant Investigator - Dr Alex Hawkey’s (Post-Doctoral Research Fellow, Western Sydney University) research in reproductive health of CALD communities will help ensure the intervention’s broad accessibility.
* Research Assistant – Miss Melissa Pehlivan (MRes/PhD Candidate, Macquarie University) is a Masters student with research experience in health psychology. Melissa will be involved in the administrative duties of the project.

Resources

The funding for this project has been confirmed by the funding body, Endometriosis Australia. The funds, $27,094 (Australian dollars) are awarded as part of Endometriosis Australia Research Grants, 2020.

Background

With 1 in 9 Australians of childbearing age living with endometriosis, this chronic condition is characterised by debilitating physical symptoms which negatively impact on their quality of life, daily activities (e.g., work, social, exercise) and mental health. This study will incorporate the lived experience of individuals with endometriosis to co-design and pilot a lifestyle-focused text message program (ENDOTEXT) to enhance the mental and physical health of those with endometriosis. Co-designed text message interventions have been demonstrated to improve health-promoting behaviours and medication adherence in individuals with chronic conditions and are a cost-efficient means of providing health education and support. Text messaging is particularly suited for young to middle-aged people (the majority of those impacted by endometriosis) because mobile phone ownership is high, little effort is required to receive the intervention, and texts can be read/re-read at times that suit users. Informed by psychological and communication theory, this study aims to develop a co-designed bank of text messages focused on providing evidence-based information about endometriosis management, healthy lifestyle behaviours (e.g., exercise, diet) and mental health support. Following co-designed development of the text message bank, piloting of the ENDOTEXT intervention will be undertaken with a sample of 160 individuals living with endometriosis.

ENDOTEXT is an innovative, co-designed program delivering patient-centred support and education in a positive way, based on women’s lived experiences and scientific evidence. Importantly, by providing education and support to the hundreds of thousands of Australian individuals living with endometriosis at little cost/time to health providers and patients, ENDOTEXT will facilitate intervention integration and scalability. Automated message delivery uses an established software system taking <2 minutes for patient enrolment, making delivery efficient with minimal labour. Since >85% of Australians aged 18-75 own a mobile phone capable of sending and receiving text messages, text message interventions have wide reach, facilitating access to health information for those in regional/remote communities. Lastly, text messages have been deemed effective for delivering health education and improving health-promoting behaviours, an important shortcoming in current endometriosis management. Directly aligning with the National Action Plan for Endometriosis, ENDOTEXT targets mental and physical health, including practical tips on managing cognitive difficulties and social isolation, which could help reduce psychological distress and facilitate people’s participation in daily activities and work. If effective, this simple and automated health solution can easily be scaled-up to support those living with endometriosis within Australia, with minimal ongoing cost.

Project Design

The ENDOTEXT message bank will be developed using an established mixed-methods process, including consumers and a research-trained citizen collaborator as co-designers. Following text message development, the ENDOTEXT intervention will be piloted in a randomised waitlist design study. Individuals (>18 years) diagnosed with endometriosis will be invited via EndoAust to participate as consumers in text message development, and in the Pilot study.

Months 1-6

Step 1: Co-design workshop. Three to four workshops (via Zoom) with approximately 6-8consumers to ensure a representative and diverse sample is recruited. Participants will determine message themes and draft positively-framed text messages consistent with clinical guidelines. Written consent from participants will be obtained prior to the commencement of the workshop, via a RedCap survey. In the initial survey, participants will be asked a series of demographic and medical questions to determine the sample characteristics. Workshops will be audio-recorded and transcribed via Zoom, stored on a secure sharepoint platform, through Macquarie University.Prof. Sherman will lead the thematic content analysis of the qualitative data, which together with ratings of the text messages, will inform any changes to draft message content.

Step 2: Text message review and refinement. Draft text message readability characteristics will be determined, with the aim being simple English at an average grade 7-8 reading level; messages above grade 8 readability will be revised. Consumers, health professionals and researchers, will each review a subset of draft text messages (20-30 messages), rated for clarity, usefulness and appropriateness. Consumers who participated in the co-design workshops will be invited via a link to a RedCap survey to their provided email addresses to review the text messages. Similarly, the project team’s researchers and clinician experts will also be invited to review the text messages via a link to a RedCap survey to their provided email. Draft messages will be reviewed to ensure they are engaging and acceptable to the target recipients. Clinician experts and researchers will also be evaluating the appropriateness of the text messages consistent with psychological and communication theory. All reviewers will be asked to rate the text messages on 3 statements on a 5 point Likert scale from strongly disagree (1) to strongly agree (5):

This message was easy to understand

The information provided in this message is useful

This message is appropriate for individuals with endometriosis

Reviewers will also be asked to provide some free-response feedback in response to the following question: Do you have any suggestions to improve this message?

Additionally, researchers and clinician experts will be required to provide informed consent and asked a few brief demographic and professional experience questions in the RedCap survey before rating the text messages. All responses will be completely anonymous.

Messages rated poorly will be edited/deleted.

Months 7-12

Pilot study. Following ENDOTEXT development, a waitlist randomised pilot study will be conducted with an additional sample (n=420) of individuals living with endometriosis recruited online through EndoAustralia. After providing consent online, participants will complete a baseline survey and then randomised to either receive ENDOTEXT (Intervention), or placed on a waitlist to receive this 3-months later if they choose (Waitlist control). ENDOTEXT participants will receive four semi-personalised text messages (e.g., to their preferred name) per week, free of charge, for a period of three months with messages selected from the ENDOTEXT message bank according to their user characteristics (e.g., smoker vs. non-smoker). At 3-months, all participants will complete a follow-up online survey, assessing:

Primary outcome: Endometriosis-specific quality of life assessed with the reliable and valid Endometriosis Health Profile Questionnaire-30 (EHP-30; Jones et al., 2006)

Secondary outcomes:

* Self-efficacy for managing endometriosis symptoms, daily activities, medication/treatment and social interactions, assessed by the reliable and valid PROMIS Self-Efficacy for Managing Chronic Conditions Short-Form 4-item subscales (Cella et al., 2010; Lee et al., 2020).
* Global health assessed by the PROMIS Global Health Short Form (Shim & Hamilton, 2019), a 10 item measure of general domains of health and functioning, including overall physical health, mental health, social health, pain, fatigue, and overall perceived quality of life.
* Psychological health measured using the widely used and validated short-version of the original DASS, the Depression, Anxiety and Stress Scales 21 item (DASS-21; Lovibond & Lovibond)
* The Perceived Consequences subscale of the valid and reliable Revised Illness Perception Questionnaire (IPQ-R; Moss-Morris et al., 2002) is a 6-item measure which will be used to assess endometriosis severity
* User acceptability (e.g., messages easy to understand)
* Perceived message impact (e.g., perception of the intervention motivating changes to exercise/diet)
* demographic/health/medical characteristics (e.g., age, education, smoking status, time since endometriosis diagnosis)

We will also collect delivery system usage data throughout the trial (e.g., delivered vs. not delivered messages, or resulted in an ‘opt out’).

To assess the feasibility of the ENDOTEXT program, participants will also be asked a series of open-ended questions regarding participants’ most and least liked messages, suggestions for program improvements and general comments.

Sample size: A power analysis was conducted using G\*Power to determine the sample size required to achieve 80% power with a critical alpha of .05. To detect a small-to-moderate change (Cohen’s *F*= 0.15) in the primary outcome, endometriosis-related quality of life (EHP-30), between the two groups (intervention and wait-list controls), a total of 350 participants at the final timepoint (3-month follow-up) is required. Assuming a conservative 20% attrition rate, approximately 420 participants will be required at baseline, distributed evenly across the groups (i.e., 245 participants per group).

Quantitative data will be collected in the secure RedCap survey platform through Macquarie University. Qualitative data will be audio-recorded and transcribed on a secure platform through Macquarie University. Data will be downloaded and only de-identified data will be distributed to investigators involved in data analysis (CI Sherman and research assistant). This sensitive level data will be shared via sharepoint and kept on this password-protected system for a minimum of 5 years since the last publication. All non-identified data will be destroyed after the de-identification process is complete.

The following data will be collected:

* Participant feedback on the proposed text content
* Demographic and medical history information
* Self-report questionnaire information on participants’ self-efficacy, global health and quality of life
* User acceptability and effectiveness of the text messages

Statistical and thematic analysis will be conducted using SPSS and nVIVO, respectively. Quantitative data will be analysed using linear mixed models to determine the impact of the text message intervention on primary and secondary outcomes at 3 month follow-up relative to controls. Results, Outcomes and Future Plans

The results of this study will be summarised and shared with participants via the nominated emails given. Results shared with participants will be a summary of the study findings and will contain no identifying information. Results will be presented without jargon in lay-persons terms and language equivalent to a 8th grade High School level.

Data will be downloaded, de-identified and stored on a secure sharepoint platform for analysis, for a minimum of 5 years since the last publication. De-identified data will also be published in a public, online data-store at the Open Science Foundation (<https://osf.io/qkxj4>). This will allow other researchers to independently verify our findings and permit the testing of new research questions using the responses. When complete, analysis of data will be reported in research papers and disseminated in academic publications.

Many of the thousands of individuals living with endometriosis feel socially isolated, unsupported, and unsure of strategies to improve health. If effective and acceptable, this novel, low-cost text-messaging intervention that aligns with the National Action Plan for Endometriosis and National Women’s Health Strategy will build capacity within the healthcare system to provide equal and ongoing support to urban, regional and rural Australians living with endometriosis. Following development and piloting of ENDOTEXT, if effective and acceptable, we will collaborate with EndoAust (AI Ciccia) to scale-up this simple and automated health solution to support Australians living with endometriosis, with minimal ongoing cost.