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Feasibility randomized controlled trial of a self-guided online intervention to promote psychosocial adjustment to unmet parenthood goals

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STUDY QUESTION: Is it feasible to implement and evaluate an online self-guided psychosocial intervention for people with an unmet parenthood goal (UPG), aimed to improve well-being, in an online randomized controlled trial (RCT)?

SUMMARY ANSWER: The evaluation of an online bilingual self-guided psychosocial intervention for people with a UPG is feasible, reflected by high demand, good acceptability, good adaptation and promise of efficacy, but minor adjustments to the intervention and study design of the RCT should be made to enhance practicality.

WHAT IS KNOWN ALREADY: Self-identifying as having a UPG, defined as being unable to have children or as many as desired, is associated with impaired well-being and mental health. Practice guidelines and regulatory bodies have highlighted the need to address the lack of evidence-based support for this population. It is unknown if MyJourney (www.myjourney.pt), the first online self-guided intervention for people with UPGs, can be implemented and evaluated in an RCT.

STUDY DESIGN, SIZE, DURATION: To evaluate the feasibility of MyJourney, we conducted a registered, two-arm, parallel group, non-blinded feasibility RCT, with a 1:1 computer-generated randomized allocation and embedded qualitative process evaluation. Participants were included between November 2020 and March 2021. Assessments were made before randomization (T1), 10 weeks (T2) and 6 months after (T3, intervention group only). Participants allocated to the intervention group received an email to access MyJourney immediately after randomization. Participants in the waitlist control group were given access to MyJourney after completing the 10-week assessment (T2).

PARTICIPANTS/MATERIALS, SETTING, METHODS: Participants were recruited via social media advertising of MyJourney and its feasibility study. People who self-identified as having a UPG could click on a link to participate, and of these 235 were randomized. Outcome measures related to demand, acceptability, implementation, practicality, adaptation and limited efficacy were assessed via online surveys. The primary outcome in limited efficacy testing was hedonic well-being, measured with the World Health Organisation Wellbeing Index (WHO-5).

MAIN RESULTS AND THE ROLE OF CHANCE: Participation and retention rates were 58.3%, 31.7% (T2) and 45.2% (T3, intervention group only), respectively. Of participants invited to register with MyJourney, 91 (76.5%) set up an account, 51 (47.2%) completed the first Step of MyJourney, 12 (11.1%) completed six Steps (sufficient dose) and 6 (5.6%) completed all Steps within the 10-week recommended period. Acceptability ranged from 2.79 (successful at supporting) to 4.42 (easy to understand) on a 1 (not at all) to 5 (extremely acceptable) scale. Average time to complete sufficient dose was 15.6 h (SD = 18.15) and to complete all Steps was 12.4 h (SD = 18.15), with no differences found for participants using MyJourney in Portuguese and English. Modified intention-to-treat analysis showed a moderate increase in well-being from T1 to T2 in the intervention group ($\eta_p^2 = 0.156$, mean difference (MD) = 9.300 (2.285, 16.315)) and no changes in the control group ($\eta_p^2 = 0.000$, MD = 0.047 (−3.265, 3.358)). Participants in the process evaluation reported MyJourney was needed and answered their needs for support (reflecting high demand and acceptability), the recommended period to engage with MyJourney was short, and their engagement was influenced by multiple factors, including personal (e.g. lack of time) and MyJourney related (e.g. reminders).

LIMITATIONS, REASONS FOR CAUTION: Participants were mostly white, well-educated, employed, childless women. Non-blinded allocation, use of self-reported questionnaire assessments and high attrition in the intervention group could have triggered bias favourable to positive evaluations of MyJourney and resulted in low power to detect T2 to T3 changes in limited efficacy outcomes.

WIDER IMPLICATIONS OF THE FINDINGS: MyJourney can proceed to efficacy testing, but future work should eliminate barriers for engagement and explore strategies to maximize adherence. Entities wanting to support people with UPGs now have a freely accessible and promising resource that can be further tested and evaluated in different settings.

STUDY FUNDING/COMPETING INTEREST(S): MyJourney's development was funded by the charity Portuguese Fertility Association, Cardiff University and University of Coimbra (CINEICC). Dr S.G. reports consultancy fees from Ferring Pharmaceuticals A/S, speaker fees from Access Fertility, SONA-Pharm LLC, Meridiano Congress International and Gedeon Richter and grants from Merck Serono Ltd. Bethan Rowbottom holds a PhD scholarship funded by the School of Psychology, Cardiff University. The other authors have no conflicts of interest.

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Key words: unmet parenthood goals / online psychosocial support / feasibility / well-being / mental health

Introduction

A growing number of people worldwide are faced with an unmet parenthood goal (UPG; e.g. Shreffler *et al.*, 2016), when they exhaust their chances to have children, or as many children as they desire, and have to adjust to this loss. People can face a UPG progressively as they experience unfavourable circumstances to trying to have children, or in a more sudden way, for instance, when finishing unsuccessful fertility treatment. Facing a UPG triggers an intense and protracted grief period and challenging adjustment process that is reported to last on average 2-years and from which some people never recover (Daniluk, 2001; Gameiro and Finnigan, 2017; Koert and Daniluk, 2017). Consistently, people with UPGs report impaired well-being and mental health (Gameiro and Finnigan, 2017). Despite practice guidelines and regulatory bodies highlighting the need to provide tailored support for UPGs (Gameiro *et al.*, 2015; HFEA, 2018), there are no accessible evidence-based interventions that can be used. Indeed, although many initiatives to support people while they are actively trying to conceive have been developed and successfully evaluated (Frederiksen *et al.*, 2015), none was designed to help people coming to terms with the fact they may never fulfil their wish for children. To address this gap in care provision, we developed MyJourney (www.myjourney.pt), a self-guided online intervention theoretically informed by the Three Task Model of Adjustment to Unmet Parenthood Goals (3TM; Gameiro and Finnigan, 2017). MyJourney resulted from a 2-year iterative development process that followed the methodology recommended by the UK Medical Research Council for the development of complex interventions (Skivington *et al.*, 2021) and integrated feedback from multiple evaluation activities (e.g. prospective acceptability study with people affected by UPGs, service evaluation with interdisciplinary and patient advisory committee, consultancy with creative and marking experts), which was reported elsewhere (Rowbottom, 2022). It applies contextual cognitive behavioural therapy to promote healthy adjustment to UPGs. It guides users through 10 steps (i.e. therapeutic activities) that target skills to build acceptance of one's UPG, find meaning in one's current situation, and move on towards other meaningful goals in life (MyJourney active components), which are expected to result in improved well-being and mental health. In this study, we applied Bowen *et al.* (2009) feasibility criteria to investigate if users use and value MyJourney, if its implementation as a self-guided online tool is feasible, and if there is the promise that it will improve users' well-being and mental health. Given the negative impact of UPGs, the lack of guidance and evidence-based interventions, and high patient dissatisfaction with current support provision (Peddie *et al.*, 2005; Gameiro *et al.*, 2015; Gameiro and Finnigan, 2017; Wischmann and Thorn, 2022), findings from this study constitute foundational knowledge to trigger further innovation in addressing this unmet support need.

MyJourney is accessible to and aims to be inclusive of anyone with an UPG. Profiling study participants (e.g. socio-demographic background, fertility history) can provide insight into the typical user of MyJourney and, more generally, of self-guided online support for UPGs. Moreover, MyJourney is totally self-guided, recommending a 10-week engagement period from users (one step per week). To promote engagement, MyJourney was designed to be used anywhere and at any time and integrates persuasive strategies such as primary task support (e.g. step-by-step guidance), dialogue support (e.g. reminders) and credibility support (e.g. knowledge and expertise demonstrations; Oinas-Kukkonen and Harjumaa, 2009). Nonetheless, it is known that users' engagement with online and mobile interventions is low, ranging between 34–64% (smartphone applications) and 50–90% (interventions evaluated within randomized controlled trials (RCTs)), especially when interventions are entirely self-guided (i.e. 30–50%; Eysenbach, 2005; Christensen *et al.*, 2009; Linardon and Fuller-Tyszkiewicz, 2020). Engagement tends to decline over time, more often when interventions are difficult to use, do not meet users' needs, and raise privacy concerns (Torous *et al.*, 2018). It was therefore considered important to ascertain users' engagement with MyJourney and if engagement is sustained over the 10-week recommended period of use. It was also important to ascertain if there are factors constraining MyJourney's implementation and user engagement. Finally, MyJourney is bilingual (English and Portuguese) and, even though its logic model was informed by research evidence and consultation involving people from Portugal, the UK and other countries, documenting differences in acceptability and demand between participants who engaged with it in English and Portuguese was considered important to evaluate the success of its adaptation (Barrera and Castro, 2006).

A recent review of digital support in reproductive medicine highlighted the lack of evidence on which patients and clinicians can evaluate available tools (Robertson *et al.*, 2022b). To ensure users can make informed decisions about whether to use MyJourney, we

evaluated its limited efficacy by estimating change in outcomes for all users, regardless of how they used MyJourney (modified intention-to-treat analysis, mITT), and only for those who completed six steps, considered sufficient dose to change outcomes, because it meant users completed at least one step associated with each active component (per-protocol analysis, PPT). Results from the only study assessing an intervention tailored to UPGs (specifically definitive childlessness; Kraaij *et al.*, 2016) provided some confidence that mental health could be improved. However, to fully capture experiences as reported by those who undergo this adjustment process, and therefore as hypothesized by the 3TM (Gameiro and Finnigan, 2017), in this study, adjustment was operationalized in a holistic way. We prioritized the assessment of positive well-being in terms of how well people feel and function (hedonic well-being—primary outcome), to capture the existential suffering experienced by most people facing an UPG. In addition, we assessed mental health and perceptions of self-realization in life (eudaimonic well-being) and personal growth (post-traumatic growth, all secondary outcomes).

In sum, after completion of the intervention development phases recommended by the UK Medical Research Council (theory and modelling; Skivington *et al.*, 2021), the main goal of this study was to gather data on uncertainties about the implementation of MyJourney. These included (i) what was the typical MyJourney user profile and whether participants independently accessed and engaged with MyJourney (demand); (ii) whether participants positively evaluated MyJourney (acceptability); (iii) whether participants engaged with the intervention as intended, whether the recommended 10-week engagement period was considered appropriate (implementation); (iv) whether there were barriers to or facilitators of engagement (practicality); (v) whether there were engagement variations between participants using MyJourney in Portuguese and English (adaptation); and (vi) whether MyJourney demonstrated limited efficacy. A second goal was to gather data on uncertainties about the acceptability and feasibility of the study protocol used to evaluate MyJourney's efficacy. The study included a qualitative process evaluation to develop a more in-depth understanding of participants' views of MyJourney and methods (Moore *et al.*, 2015). Results, reported according to the CONSORT guidelines for feasibility and pilot studies (Eldridge *et al.*, 2016), will inform modifications to be done in MyJourney and in the study protocol to test efficacy via RCT. Results can also be informative for the implementation of other interventions tailored to UPGs and fertility care more generally, in particular when self-guided and online.

Materials and methods

Design

Registered (www.Clinical-Trials.gov, NCT04850482), two-arm, parallel-group, non-blinded feasibility study with 1:1 computer-generated randomized allocation to the intervention group (immediate access to MyJourney) or waitlist control group (access to MyJourney after 10 weeks). There were three assessment moments: baseline (pre-exposure to intervention, T1), 10 weeks after baseline (post-exposure to intervention, T2), including a 1-h semi-structured individual interview for process evaluation participants only and 6 months after baseline (intervention participants only, T3).

Procedures

Individuals who clicked the button to take part in the study were presented with the information sheet and informed consent. Participants who fit inclusion criteria and consented were allocated a random Study ID and invited to complete the T1 assessment (Qualtrics survey, Copyright 2021, Qualtrics, Provo, UT, USA), after which they were randomized to the intervention or waitlist control groups. Ten weeks after, participants were invited by email to complete the T2 assessment, after which waitlist control participants were debriefed (which included provision of a summary of the study and support contacts) and given access to MyJourney. Six months after intervention group, participants were invited by email to complete the T3 assessment, after which they were debriefed. Reminder emails and SMS were sent 4, 7 and 10 days after email invitations to register an account with MyJourney and complete assessments. If participants did not complete assessments after all reminders, they were sent a short exit survey to determine reasons for withdrawal and provided with the debriefing. Two weeks after being invited to complete the T2 assessment, participants from the intervention and control groups were emailed an invitation and consent form to take part in a semi-structured Zoom interview for process evaluation.

Participants

Recruitment took place between November 2020 and March 2021. A Facebook page and Twitter account with information about MyJourney and the study were created and disseminated by fertility charities (e.g. Fertility Network UK, Portuguese Fertility Association) and advocates and support groups, via their website, social media, blogs or newsletters. The study was also disseminated via the Prolific recruitment platform. Interested people were directed to MyJourney's landing page, where they could register for the study. Consenting participants could opt into a prize draw to win one of ten £20 vouchers at each assessment moment, and participants who took part in the process evaluation were offered £15 (intervention) and £10 (control) voucher tokens.

Inclusion criteria were being adult, able to give consent, self-identifying as having an 'unfulfilled wish for children', able to access and use MyJourney (have an internet connection, suitable device and active email address), understanding English or Portuguese, and able to answer questionnaires. Exclusion criteria were having been diagnosed with a mental-health disorder within the last 2 years, currently receiving therapy for a diagnosed mental-health problem or being unable to use MyJourney due to other health problems (e.g. vision impairments), all self-reported.

Intervention

The intervention, described using the Template for Intervention Description and Replication (TIDieR; Hoffmann *et al.*, 2014), is called MyJourney and is available in English and Portuguese. The 3TM (Gameiro and Finnigan, 2017) informed the hypothesized active components targeted by MyJourney. Supplementary Fig. S1 presents the logic model that informed MyJourney. Cognitive Contextual Behaviour Therapy, focussing on a person's relationships with their thoughts, emotions and behaviours (Hayes *et al.*, 2006; Neff and Germer, 2013), was the chosen therapeutic framework.

MyJourney is an online web app accessible at www.myjourney.pt. MyJourney's landing page includes information about who MyJourney is for, what users can expect and the benefits of engaging with it. Any number of people can engage with MyJourney at the same time, and at times that are convenient to them, as it is available online and used individually. For the duration of this feasibility study, only participants meeting eligibility criteria could access MyJourney.

To use MyJourney, users create an account and complete registration details. MyJourney's content is separated into 10 ordered steps that are found in the 'Map' area. Each step is a structured activity designed to promote a specific therapeutic skill that is linked to a theorized active component (see Supplementary Fig. S1). When users complete each step, they unlock up to three optional therapeutic resources called Routines, which are added to the 'Backpack' area and encourage users to practice the therapeutic skill they are developing. The steps and routines use a variety of activities to engage users, including writing, reflecting and mindfulness meditations. On completion of step 10, users have access to a 'Looking Ahead' Routine targeting relapse prevention. It encourages users to recognize the changes experienced since starting to use MyJourney and the appropriate therapeutic skills to use in future challenging situations.

At the start of each step, users complete a well-being assessment (WHO-5, Life Satisfaction and Happiness scales, see Table I and Supplementary Table SI). They are then fed back their WHO-5 score in comparison to normative values, with information to interpret it. This information recommends users who score below 50 repeated times or below 28 at any time (Topp *et al.*, 2015) to seek additional support (e.g. accredited mental health professional) and includes a link to a list of support contacts (www.myjourney.pt/support).

Users are recommended to engage with one step per week, totalling 10 weeks, but told they can engage at their own pace. Each step takes ~5 min to read, and users have the flexibility to answer the questions or concepts introduced for as long as they wish. Answers that users enter in some steps are displayed in the following steps, providing a sense of personalization. Answers are not mandatory, but users are encouraged to do them with short pop-up messages. Email reminders from MyJourney, for example to engage with the next step, are pre-set at weekly intervals, but users have the option to amend this to suit their preferences.

Feasibility outcomes

Feasibility outcomes are described in Table I. The hypotheses for this study were operationalized using traffic-light progression criteria for each feasibility outcome (Avery *et al.*, 2017), presented in Supplementary Table SII. To progress to efficacy evaluation, all feasibility outcomes for the MyJourney intervention and study protocol should meet the criteria to proceed (green) or proceed with amendments (amber).

Materials

The T1 questionnaire assessed participants' socio-demographics, UPG journey status, engagement with other support sources and recruitment method (the latter two not reported here). T1 and T2 questionnaires assessed MyJourney's active components (not reported) and study outcomes. The T2 and T3 questionnaires also assessed the perceived impact of the COVID-19 pandemic (not reported) and evaluation of the intervention (intervention group only) and study protocol (T2 only).

Socio-demographics

Questions were age (in years), gender (0 = female, 1 = male), country of residence, relationship status (0 = single/divorced/widowed, 1 = in relationship), education (0 = no University education, 1 = University education), employment status (0 = unemployed/student/retired, 1 = employed part/full time) and ethnicity.

UPG history

Questions were parental status (0 = no children, 1 = children, including stepchildren), whether participants still had a child wish (0 = no, 1 = yes) and if they had done fertility treatment in the past (0 = no, yes = 1). Participants were asked to indicate their UPG journey status on a scale with seven options corresponding to the six Stages of Change Model (Prochaska *et al.*, 2002) and an other/don't know option. These were coded into five categories: not trying to accept [precontemplation, contemplation], trying to accept for less than 6 months [preparation, action], trying to accept for more than 6 months [maintenance], accepted [termination], other/don't know.

Feasibility outcomes

All materials, including limited efficacy primary and secondary outcomes and the process evaluation, are described in Table I.

Sample size

Previous research (e.g. Cousineau *et al.*, 2008; Kersting *et al.*, 2013; van Dongen *et al.*, 2016) indicated around 60% of interested people would be eligible, consent and complete the T1 assessment, from these, 80% would register to MyJourney, and from these 70% would complete the T2 assessment, suggesting participation and retention rates of 60% and 34%, respectively. Recruiting 152 participants, a participation rate of 60% to within a 95% CI of ±8% and completion rate of 34% to within a 95% CI of ±7% could be estimated, and a final sample of 50 (25 per group) at T2 could be obtained (assuming equal attrition in two arms). The latter represents enough power to detect moderate-to-large effect-size differences in limited efficacy testing with a mixed-factorial design (G*power, $f = 0.25$, alpha = 0.05, power = 0.90; Mayr *et al.*, 2007).

Randomization

Randomization occurred after the T1 assessment. Participants were stratified into an English and Portuguese speaking group, indicated by their choice of language, and both groups were randomized in a 1:1 ratio via computer-generated randomization. Participants and researchers were informed of the randomization result.

Data analysis

Quantitative data were analysed using IBM SPSS Statistics for Windows Version 25. Continuous variables were presented with means and SD or SEM and categorical variables with absolute numbers and percentages (%). Extreme outliers (greater/less than 3× interquartile range outside of the upper/lower hinge of the boxplot) were removed from the analysis. Differences between groups were examined via t and χ^2 tests.

Table I Feasibility outcomes for the MyJourney intervention and study protocol and assessment materials used.

	Bowen's dimension	Outcomes and materials
MyJourney intervention	Demand	• Number of participants who registered, set up account and completed steps 1–10; time spent overall; total number of visits; time spent on steps and routines; and number of times these were visited: data stored by MyJourney
	Acceptability	• Quantitative ratings regarding successful in supporting people with unmet parenthood goals, user-friendly interface, visually appealing, easy to understand, inclusive, trusted content, well-being feedback useful: Likert-scale questions ranging from 1 (strongly disagree/not at all) to 5 (strongly agree/extremely). • Steps' usefulness and challenge: data automatically stored by MyJourney • Number of participants who would recommend MyJourney to others and intend to keep using (also at T3): dichotomous yes/no questions.
	Implementation	• Responses to open-ended questions about technical issues and appropriateness of 10-week recommended engagement period
	Practicality	• Number of participants who used MyJourney as intended (completed 10 steps) and completed the sufficient dose during the 10-week recommended engagement period; time taken to use MyJourney as intended and complete the sufficient dose: data stored by MyJourney
	Adaptation	• Differences in number of participants engaging with intervention in Portuguese and English who registered, started step 1, completed the sufficient dose and used as intended; differences between participants engaging with intervention in Portuguese and English in hours spent overall and total number of visits: data stored by MyJourney
	Limited efficacy*	• Modified intention-to-treat (mITT, all participants randomized) and per protocol (PP, only participants who received a sufficient dose) analyses on primary (hedonic well-being) and secondary outcomes (eudaimonic well-being, mental health, post-traumatic growth) measured at T1, T2 and T3 • Primary outcome: hedonic well-being (WHO-5: World Health Organization Wellbeing Index; Topp *et al.*, 2015). The WHO-5 is translated to 31 languages, has population mean scores for most European countries (see Topp *et al.*, 2015, Supplementary Table SI and https://www.eurofound.europa.eu/data/european-quality-of-life-survey), can be used to screen for clinical depression, and provides a 10-point increase as the threshold to determine clinically relevant improvements. • Secondary outcomes: eudaimonic well-being (three single-item questions: life is worthwhile, satisfaction with life, happiness; Eurofound, 2017; Office for National Statistics, 2012), mental health (Mental Health Inventory; Ware *et al.*, 2000) and post-traumatic growth (Post-traumatic Growth Inventory—Short Form; Cann *et al.*, 2010)
Study protocol	Demand	• Participation and retention rates and reasons for non-participation/withdrawal
	Acceptability	• Proportion who completed T1, T2 and T3 assessments
	Implementation	• Reported issues relating to study procedures or materials
	Practicality	• Time taken to complete assessments and process evaluation interviews, and researcher's time to administer the study
	Adaptation	• Participation and attrition rates according to language of engagement with MyJourney
Process evaluation	All dimensions	• The script for the semi-structured interviews included 16 questions covering MyJourney's acceptability (5 questions, e.g. aspects of MyJourney particularly enjoyed or helpful), demand (2 questions, e.g. expectations about MyJourney), implementation and practicality (3 questions, e.g. mode of technology used to engage with MyJourney), as well as the study methods (6 questions, e.g. how demanding was the study). Participants were prompted for additional suggestions or comments.

All assessments were made at T2 except when otherwise indicated.
*All questionnaires are sound and widely used, with higher scores indicating more of the construct. Questionnaires are described in detail in Supplementary Table SI.

Limited efficacy was reported for mITT (all participants who completed T1 and T2) and per protocol (PP, only participants who completed up to step 6). Two-way mixed ANOVAs and MANOVAs (for eudaimonic well-being measures) were computed to analyse limited efficacy on the study outcomes, with Group (MyJourney intervention, Waitlist control) as the between-subject variable and Time (T1, T2) as the within-subject factor. Repeated ANOVAs and MANOVAS with Time (T2, T3) as the within-subject factor were computed to investigate changes in outcomes from the 10 weeks to the 6-month follow-up in the MyJourney intervention group only. Effect sizes (partial eta squared, η_p^2, small = 0.01, medium = 0.06, and large = 0.14) were reported (Cohen, 1992). Mean difference and 95% CI were reported for Group and Time main effects and for simple effects, when significant Group by Time interactions were found. Finally, we used χ^2 tests to investigate if the proportion of participants who experienced a clinically significant improvement in the primary outcome hedonic well-being from T1 to T2, defined as a minimum 10-point increase in the WHO-5 questionnaire (Topp *et al.*, 2015), differed in the MyJourney intervention and waitlist control groups. $P < 0.05$ indicated statistical significance.

Process evaluation interviews were audio-recorded, transcribed verbatim and analysed with thematic analysis (Braun and Clarke, 2006) using QSR International's NVivo 12 Software. This involved familiarization with the data by repeatedly reading through the transcripts, followed by inductive generation of codes (that described a piece of information present in the data), which were organized according to Bowen *et al.* (2009) feasibility criteria. Themes were developed from analogous data, but attention was also given to divergent data if it was strongly endorsed by participant(s). E.D. and B.R. performed the analysis, with B.R., S.G. and E.D. coming together repeatedly for peer debriefing, discussion and agreement of codes.

Ethical approval

The School of Psychology Research Ethics Committee, Cardiff University provided approval (E.C.20.10.13.6082).

Results

Participant flow

Figure 1 presents the participant flowchart. During the 5 months recruitment period, 440 people accessed the study, but 25 did not meet inclusion criteria and 12 were duplicated accesses of the same person. Of the 403 remaining (92% eligibility rate), 235 completed the T1 assessment and were randomized (58.3% participation rate). From these, 42 out of 108 participants in the MyJourney intervention group (38.9%) and 86 out of 111 participants in the waitlist control group (77.5%) did the T2 assessment. Nineteen out of 42 participants in the intervention group (45%) did the T3 assessment.

Sample characteristics

Table II presents the sample characteristics. Most participants were women, white, had university education, and were in a relationship.

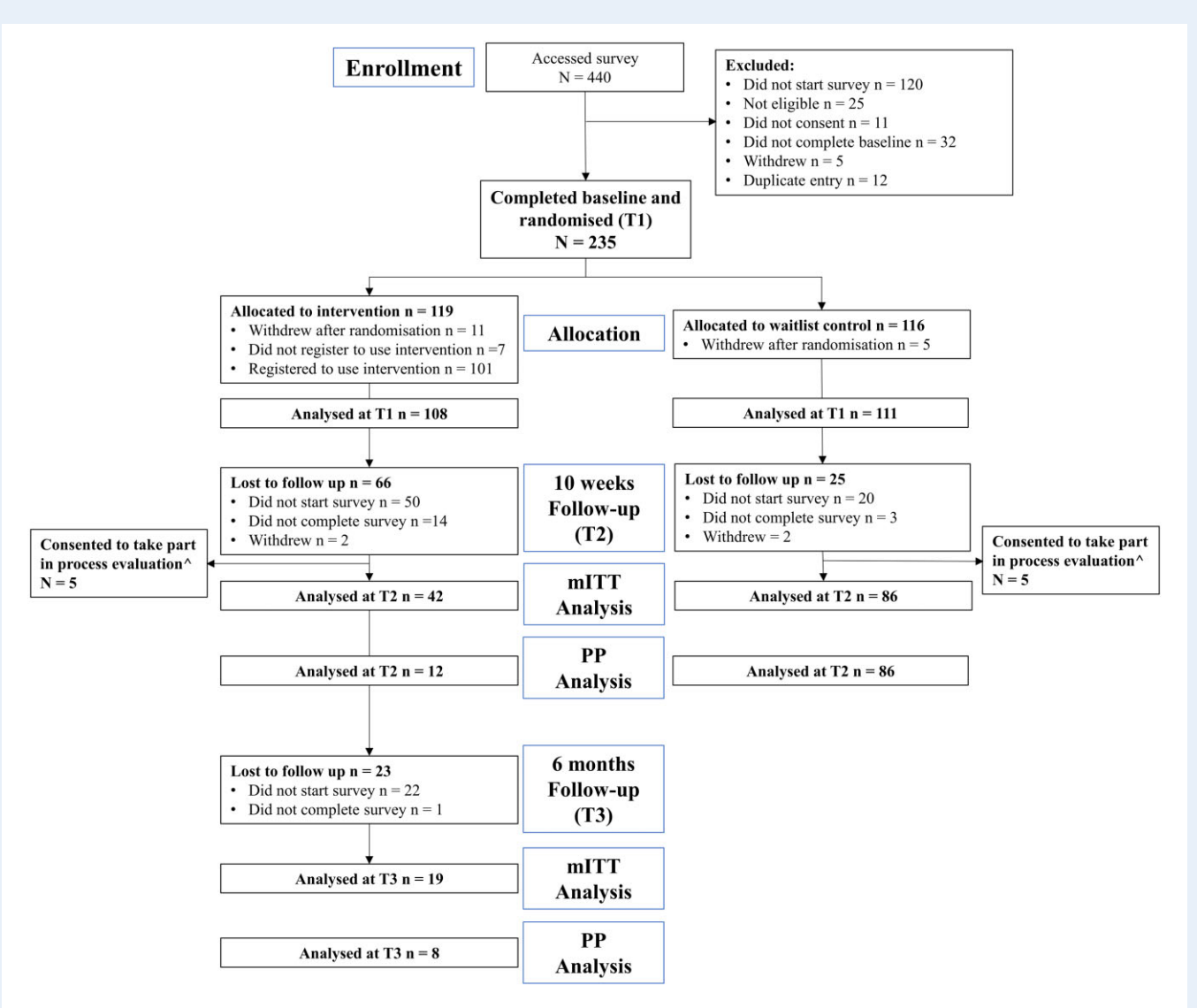

Figure 1. Participant flowchart.

Table II Baseline characteristics of the MyJourney intervention and waitlist control groups (N = 219).

Variable	MyJourney intervention (N = 108)	Waitlist control (N = 111)
Socio-demographic		
Age in years, mean (SD)	39.3(10.05)	39.0 (9.05)
	N (%)	**N (%)**
Female	92 (85.2)	100 (90.1)
In relationship	83 (76.9)	92 (82.9)
University education	86 (79.6)	83 (74.8)
Employed part/full time	92 (85.2)	90 (81.1)
Ethnicity^ (N = 148)		
White	64 (90.1)	72 (93.5)
Other	7 (9.9)	5 (6.5)
Country		
UK	42 (38.9)	46 (41.4)
Portugal	35 (32.7)	33 (29.7)
Rest of Europe	17 (15.7)	24 (21.6)
USA	8 (7.5)	3 (2.7)
Rest of world	5 (4.7)	5 (4.5)
UPG journey status		
Sustained child wish	90 (83.3)	94 (84.7)
With children	14 (13.0)	17 (15.3)
Had done fertility treatment in the past	60 (55.6)	73 (65.8)
UPG journey status		
Not trying to accept	27 (25.0)	27 (24.3)
Trying for less than 6 months	34 (31.5)	34 (30.6)
Trying for more than 6 months	39 (36.1)	41 (36.9)
Already accepted	4 (3.7)	2 (1.8)
Other/don't know	4 (3.7)	7 (6.3)
Engaged with support in the past	48 (44.4)	63 (56.8)
Currently engaged with informal support	25 (23.1)	25 (22.5)

UPG, unmet parenthood goal. ^Ethnicity question not presented to Portuguese participants.

Average age was 39 years. Forty per cent of participants were from the UK and 31% from Portugal. The vast majority still sustained a child wish, only 14% had children, and 61% had engaged in fertility treatment in the past. The intervention and waitlist control groups did not differ in socio-demographic and UPG journey status. However, overall participants not completing T2 were more likely to be younger, reside in Europe (excluding UK and Portugal), and to have been recruited via Prolific (data not shown).

Feasibility of MyJourney intervention

Demand

Supplementary Fig. S2 shows the proportion of participants who completed each MyJourney Step, in total and according to stage of UPG journey. Of the 108 participants who received the link to register, 101 (84.9%) registered and 91 (76.5%) completed their account set up. Fifty-one (47.2%) participants completed the first Step of MyJourney, 12 (11.1%) completed six steps (sufficient dose), and six (5.6%) completed all 10 steps within the 10-week recommended engagement period. Comparisons by stage of UPG journey could not be done. Participants accessed 0.23 routines (SD = 1.5, range 0–22), for 1.4 min (SD = 1.6, range = 0.1–8.9). On average, participants used MyJourney for 10 h (SD = 18.08, range 0.04–79.37) and accessed it eight times (SD = 5.38).

Acceptability

Acceptability ratings for participants in the mITT and PP analysis are presented in Fig. 2. Most participants would recommend MyJourney to someone else in a similar situation. At T2, the majority intended to keep using it but this proportion was lower at T3 because, from those who completed all MyJourney steps (i.e. reached end of intervention), three in four did not intend to continue using it. Ratings on the usefulness and challenge of steps are presented in Supplementary Fig. S3. Usefulness ratings were moderate to high, with step 5 'Illuminate your journey' having the lowest rating (3.31, SEM = 0.35) and step 10 'Looking Ahead' having the highest (4.17, SEM = 0.40). Challenge ratings were low to moderate, with step 8 'Connect with others' having the lowest rating (2.57, SEM = 0.43) and step 6 'Plan your route' having the highest (3.42, SEM = 0.40).

Implementation

Thirty-one (73.8%) participants provided a comment on whether they experienced technical issues. The majority did not (23, 74.2%), 3 (9.7%) experienced issues registering, 3 (9.7%) felt the login process was not accessible and 2 (6.5%) reported other issues (i.e. missing content or data not being saved). Twenty-five participants (59.5%) commented on the 10-week recommended engagement period. Twelve (48.0%) felt it was the right amount of time, 7 (28.0%) felt that it was too short, 5 (20.0%) felt there should be unlimited time to engage and 1 (4.0%) thought it was too long.

Practicality

Six (5.6%) participants used MyJourney as intended (completed 10 steps), taking 12.4 h (SD = 16.66, range = 2.21–37.30) to do so, and 12 (11.1%) completed the sufficient dose (completed six Steps) taking 15.6 h (SD = 18.15, range = 1.53–53.25).

Adaptation

Portuguese speaking participants were significantly more likely to start the first Step than English speaking participants (96% versus 63%, χ^2 (1) = 8.53, P = 0.004), but there were no statistically significant differences regarding registration, completion of sufficient dose, use as intended, hours spent using MyJourney and number of visits.

Limited efficacy

Descriptive statistics for the study outcomes for the MyJourney intervention and Waitlist control groups at baseline (T1), 10 weeks (T2) and 6 months (T3) follow-ups are presented in Table III. Supplementary Tables SIII and SIV present F ratios, effect sizes and mean differences (95% CI) for the mixed ANOVAs and MANOVAs testing limited efficacy and changes from the 10 weeks to the 6-month follow-up in the MyJourney intervention group, respectively.

Primary outcome Figure 3 presents means and SEMs in hedonic well-being for the MyJourney intervention and Waitlist control groups

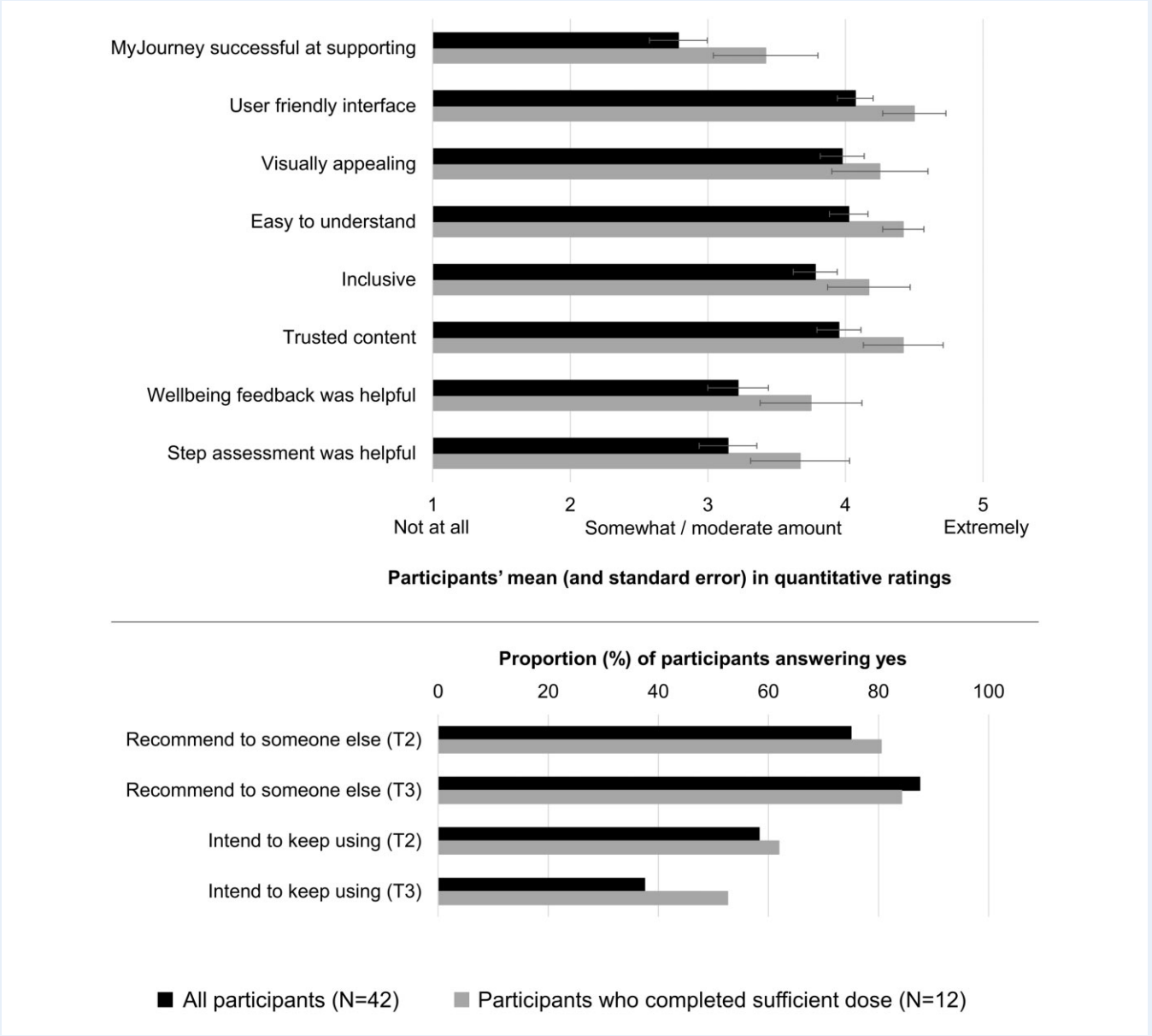

Figure 2. Acceptability ratings of MyJourney.

across assessment times. In the mITT analysis, the mixed ANOVA for hedonic well-being showed significant main effects from Group and Time, which were qualified by a significant interaction of Time by Group. Simple effect tests showed a large increase in hedonic well-being in the MyJourney intervention group from T1 to T2, while no change was observed in the control group. The repeated-measure ANOVA investigating changes in hedonic well-being from T2 to T3 showed a non-significant effect of Time. Seventeen (40.5%) and 15 (17.4%) participants in the MyJourney intervention and Waitlist control groups, respectively, reported a clinically significant improvement in hedonic well-being from T1 to T2. The difference in proportions was statistically significant (χ^2 (1) = 6.63, P = 0.010).

In the PP analysis, the mixed ANOVA for hedonic well-being showed significant main effects from Group and Time, which were qualified by a significant interaction of Time by Group. Simple effect tests showed a large increase in hedonic well-being in the MyJourney intervention group from T1 to T2, while no change was observed in the control group. The repeated-measures ANOVA investigating changes in hedonic well-being from T2 to T3 showed a significant effect of Time, indicating that participants in the MyJourney intervention group reported a large increase in hedonic well-being across this period. Six (40%) and 15 (17.4%) participants in the MyJourney intervention and Waitlist control groups, respectively, reported a clinically significant improvement in hedonic well-being from T1 to T2. The difference in proportions was statistically significant (χ^2 (1) = 7.99, P = 0.005).

Secondary outcomes In the mIIT analysis, the MANOVA investigating limited efficacy on eudaimonic well-being, subsequent ANOVAs for its three measures, and the ANOVA investigating limited efficacy on

Table III Descriptive statistics (mean, SD) for the study outcomes at baseline (T1), 10-week (T2) and 6-month (T3, MyJourney intervention group only) follow-ups.

Variables	Time	MyJourney intervention		Waitlist control
		mIIT N = 42 Mean (SD)	PP N = 12 Mean (SD)	N = 86 Mean (SD)
Hedonic well-being, range 0–100	T1	49.4 (20.8)	48.0 (21.7)	44.0 (19.4)
	T2	58.7 (17.1)	63.3 (10.4)	44.0 (19.9)
	T3	61.1 (16.5)	70.0 (8.3)	–
Eudaimonic well-being				
Life is worthwhile, range 0–10	T1	6.4 (2.42	6.0 (3.0)	5.6 (2.4)
	T2	7.1 (2.0)	7.2 (1.3)	5.8 (2.4)
	T3	7.1 (1.8)	7.8 (1.0)	–
Satisfaction with life, range 1–10	T1	6.1 (1.8)	5.3 (2.1)	5.7 (2.0)
	T2	6.7 (1.9)	6.9 (1.2)	5.9 (2.1)
	T3	6.9 (1.5)	7.4 (.5)	–
Happiness, range 1–10	T1	6.1 (1.8)	5.3 (2.1)	5.6 (1.9)
	T2	6.6 (1.8)	6.9 (1.2)	5.9 (2.1)
	T3	7.0 (1.5)	7.5 (0.8)	–
Mental Health, range 0–100	T1	57.7 (18.1)	57.3 (20.4)	51.9 (18.0)
	T2	59.8 (18.2)	65.3 (13.5)	54.7 (20.1)
	T3	67.6 (16.1)	76.0 (5.7)	–
Post-traumatic growth, range 0–50	T1	23.2 (10.3)	24.2 (10.0)	21.6 (10.7)
	T2	27.4 (10.2)	29.6 (10.4)	22.3 (11.2)
	T3	24.3 (13.3)	28.7 (12.5)	–

Descriptives for the MyJourney intervention group are presented for all randomized participants who completed the T2 assessment (modified intention-to-treat analysis, mITT) and only for those who received a sufficient dose (per-protocol analysis, PP).
mITT, modified intention-to-treat analysis; PPT, per-protocol analysis. For all variables higher scores indicate more of the construct.

post-traumatic growth showed significant main effects of Time, indicating that, regardless of group, participants reported a moderate increase in eudaimonic well-being and post-traumatic growth from T1 to T2. The repeated-measure ANOVAs investigating changes in eudaimonic well-being and post-traumatic growth from T2 to T3 in the MyJourney intervention group revealed non-significant effects. Finally, no significant effects were observed in the mixed ANOVA investigating limited efficacy on mental health, but a significant effect of Time was found for the repeated ANOVA investigating changes in mental health from T2 to T3 in the MyJourney intervention group. A large increase in mental health in the MyJourney intervention group was observed.

In the PPT analysis, the mixed MANOVA investigating limited efficacy on eudaimonic well-being and subsequent ANOVA for life is worthwhile showed a significant main effect of Time, indicating that, regardless of group, participants reported a moderate increase in their perceptions that their lives were worthwhile from T1 to T2. For satisfaction with life and happiness, the main effect of Time was qualified by a significant interaction of Time by Group. Simple effect tests showed large increases in satisfaction with life and happiness from T1 to T2 in the MyJourney intervention group. The Waitlist control group showed no change in satisfaction with life and a moderate increase in happiness. No significant effects were found for mental health and post-traumatic growth in the mixed ANOVAs testing limited efficacy and repeated-measure ANOVAS testing changes from T2 to T3 in the MyJourney intervention group.

Feasibility of study protocol

Demand

Participation rates were 58.3%, and retention rates were 31.7% (T2) and 45.2% (T3, intervention group only), respectively. Twelve (5.5%) participants completed the exit survey providing reasons for withdrawal: five related to acceptability (e.g. dissatisfaction with language), three to implementation (e.g. unable to register with MyJourney) and four to practicality (e.g. lack of time).

Acceptability

Of participants emailed to fill assessments, 83.0% (235/283), 58.4% (128/219) and 45.2% (19/42) completed the T1, T2 and T3 assessments, respectively. Control group participants were more likely to complete the T2 assessment than intervention group participants (77.5% versus 38.9%, $\chi 2$ (1) = 15.54, $P < 0.000$).

Implementation

Over the 8-month period of the study, 19 (8.1%) participants sent email queries. Thirteen (67%) concerned access or technical issues with the intervention, 2 (11%) expressed a wish to withdraw from the

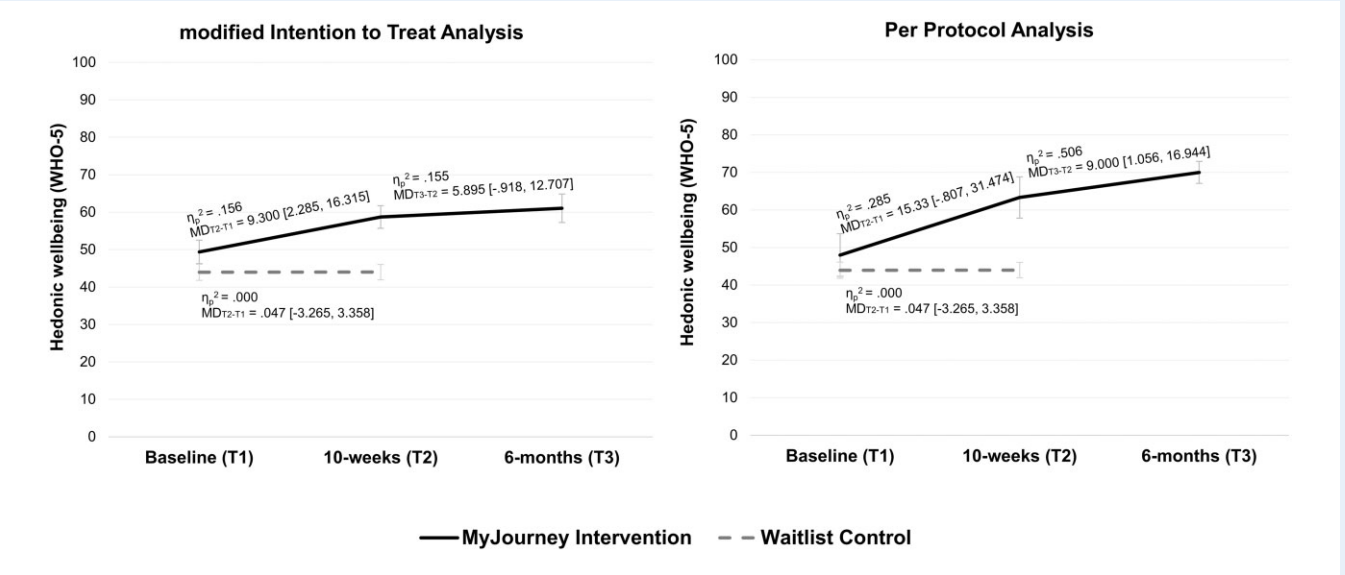

Figure 3. Means and SEM for each group on hedonic well-being (WHO-5) across assessment times. The effect size (partial eta-squared, η_p^2, small = 0.01, medium = 0.06 and large effect size = 0.14) of changes across assessment times for each group is also reported, along with the mean difference (MD) estimate and its [95% CI].

study, 2 (11%) expressed dissatisfaction with language used in questionnaires and 2 (11%) were related to errors in the email sent from the study (e.g. intervention registration link missing on email).

Practicality

On average participants took 22 (SD = 11.97), 23 min (SD = 20.67) and 8 min (SD = 5.81) to complete the T1, T2 and T3 assessments, respectively. Process evaluation interviews ranged from 9.56 to 52.20 min (mean = 24.42, SD = 9.49). It took on average 44 min (SD = 19.72, range 15–240) a day for researchers to administrate the study over a period of 8 months.

Adaptation

Participation rates for English and Portuguese participants were 59.0% and 46.7%, respectively ($\chi 2$ (1) = 5.73, P = 0.017), and retention rates were 35.8% and 25% at T2, respectively ($\chi 2$ (1) = 7.23, P = 0.007) and 23.8% and 21.4% at T3, respectively ($\chi 2$ (1) = 0.861, P = 0.353).

Adverse effects

No adverse effects were observed nor reported by participants.

Process evaluation

Ten interviews with participants from the MyJourney intervention (n = 5) and Waitlist control (n = 5) were run. No participants had children. All but one sustained a child wish, seven had been trying to accept their unfulfilled wish for children for more than 6 months, two for less than 6 months and one was not trying to accept. All intervention and control group participants had started using MyJourney and commented on it during the interview. Level of engagement with MyJourney varied from starting step 1 to completing step 10 in the intervention group and from completing step 3 to completing step 7 in the control group. Thematic analysis resulted in nine themes, organized under three meta-themes, presented in Table IV, along with illustrative quotes from participants. The meta-themes were 'MyJourney is acceptable and meets demand for support', 'Flexible engagement with MyJourney was valued and practical, but this engagement was multidetermined', 'The study protocol is acceptable and feasible'. Themes and meta-themes reflected that there is demand for MyJourney, it is acceptable and seems to produce the expected benefits, that multiple factors, both related with MyJourney (e.g. stage of UPG journey, reminders) and not (e.g. lack of time) determine variability in engagement over time, and that flexibility to use MyJourney at own time and pace is highly valued. The study protocol was considered feasible.

Progression criteria

The progression criteria met in this feasibility study are presented in Supplementary Table SV. Of the nine criteria set, three (33%) met criteria to proceed (green), indicating that more than half of participants in the intervention group would recommend MyJourney to others, more than half were eligible and more than half of these were recruited. The remaining six (67%) met criteria to proceed with amendments (amber), indicating that 10–50% of participants started using MyJourney, most step usefulness and challenge ratings were moderate (>3 and <3, respectively), between 10% and 50% of participants completed sufficient dose within the 10-week recommend engagement period, between 20% and 80% of participants were lost to follow-up and between 30% and 70% of participants completed assessments.

Discussion

Results demonstrate that MyJourney and its efficacy evaluation protocol are feasible. There is demand for MyJourney, it is acceptable and beneficial to its users, and implementation is feasible for Portuguese and

Table IV Themes and meta-themes from process evaluation interviews.

Meta themes	Themes and their description	Quotes
MyJourney is acceptable and meets demand for support	**Support is needed and sought out.** Participants perceive demand for MyJourney due to the challenges faced by having an UPG. Around half had already tried alternative methods of support and most were members of peer support groups.	'*I was just isolated with it, there was no one else going through it, there was no one else to talk to . . . my mental health really suffered, really really suffered at that time*' (IT2, 52, EN) '*I did CBT um a couple of years ago, just to really help me overcome somethings*' (WL1, 43, EN) '*I am a member of a support group and we meet regularly and talk about these sorts of things*' (IT5, 39, PT)
	MyJourney satisfies need for support. A majority were grateful for MyJourney, felt it satisfied their need for support and were glad that research on UPGs was being carried out.	'*You very quickly get support, it does feel very supportive, even though it's very individual*' (WL2, 42, EN) '*I think the reason I wanted to get involved was because it's like, oh my god wow, somebody is helping, somebody is even acknowledging that this is a really difficult thing*' (IT2, 52, EN)
	MyJourney is acceptable. MyJourney was considered acceptable and its features, including mindfulness, valued to address UPGs and other life domains. Nonetheless, half of participants had suggestions for improvement.	'*I think the meditation part is awesome. It's very important for those who already practiced it and those who didn't . . . I found it very good*' (IT4, 37, PT) '*There could possibly be some more work on making it more customer friendly in a certain sense*' (WL5, 48, EN)
	MyJourney targets expected outcomes. A majority felt that MyJourney provided strategies and support to 'move on', including managing emotions and enhancing well-being.	'*Teach yourself to sort of let go of some of it and that it's ok to leave some of those bits of luggage behind . . . so that one was useful*' (IT1, 44, EN) '*I suppose it's that journey bit, but it's that sort of moving, moving you forward and giving you those strategies and those supports to be able to do that*' (WL2, 42, EN)
Flexible engagement with MyJourney was valued and practical, but this engagement was multi-determined	**MyJourney is flexible.** All participants valued the flexibility to engage with MyJourney as and when they wanted. Most reported not engaging with one Step per week.	'*Working through it at your own pace, and your own time is hugely beneficial*' (WL2, 42, EN) '*Even though I used it on my own, with time, it took me some months . . . I found it very good*' (IT4, 37, PT)
	MyJourney is practical. A majority felt engagement with MyJourney was practical, but a minority referred to less practical aspects such as needing to use MyJourney on a larger screen.	'*This is one of the best parts, being always available*' (IT4, 37, PT) '*I engaged with it on my phone, which was a regret . . . in hindsight I wouldn't have put it on my phone, I would have yeah, used it on a larger screen device*' (IT3, 39, PT)
	Engagement is multidetermined. Engagement was influenced by many factors, e.g. views about MyJourney, stage of journey, barriers e.g. work commitments or reminders going into the spam folder, and a desire to take one's time.	'*Maybe it is geared for people who are, yeah at the earlier stages, haven't quite, you know are sort of still flip flopping from one stage of grief to the other*' (IT1, 44, EN) '*It went about 2 weeks and I hadn't logged in, I just forgot, busy with work and life and things*'(WL3, 38, EN) '*Perhaps had the emails that went into my spam folder arrived, I'd perhaps might of engaged a little bit more*' (IT4, 37, PT) '*I'm thinking maybe I'll give myself more than a week to do each step just to make sure I'm covering everything in the backpack*' (WL1, 43, EN)
The study protocol is acceptable and feasible.	**Study methods are acceptable and appropriate.** Overall, all participants felt the study methods were appropriate and a majority felt they weren't too demanding.	'*I thought the questionnaires were good, they asked the right kind of questions in the right way, you know . . . they were nicely asked and the wording was nice*' (WL3, 38, EN) '*Not demanding at all. It was not mandatory to complete all the parts; we could go back, amend, move forward*' (IT4, 37, PT)
	Study design was understood by some. A minority reported understanding why randomization was important.	'*I knew I had a like, 50/50 chance of one or the other, and I thought yeah I'll participate irrespective of which group I get randomised into*' (IT1, 44, EN)

IT, intervention group; WL, waitlist control group, age in years provided; EN, interview conducted in English; PT, interview conducted in Portuguese.

English users. As with other online self-guided interventions, sustained engagement over time can be challenging and is affected by multiple factors, including lack of time and technical issues. MyJourney demonstrated limited efficacy for the primary outcome (hedonic well-being) and a secondary outcome (eudaimonic well-being), with clinically relevant improvements in hedonic well-being observed in half of the intervention participants. Process evaluation uncovered how perceived benefits were consistent with MyJourney's logic model and underlying 3TM. Overall, the study protocol to evaluate MyJourney is feasible, but there was considerable attrition in the intervention group which could be linked with declining engagement with the intervention. As all progression criteria were met development should continue to efficacy evaluation without significant changes to MyJourney's logic model or content, but with adjustments to both intervention and study protocol.

Results show there is demand for MyJourney and that its availability is valued. Demand appears to come from white, well-educated and employed childless women at all stages of their acceptance journey and who are experiencing lower than average well-being and mental health. It is unclear if this is the profile of people who seek support for UPGs or is specific to MyJourney. The only other known intervention for people with UPGs did not report on demand (Kraaij et al., 2016); therefore, it is challenging to contextualize our findings. It is worthwhile noting that one in four users was not yet trying to accept their UPG. These users seemed to progress through MyJourney in the same way those trying to accept did, suggesting both groups find something useful in MyJourney. Qualitative data highlighted feelings of gratitude and satisfaction towards the support provided by MyJourney. Taken together results provide confidence that there is unmet demand for UPG support, that MyJourney is one viable solution to address it and that other initiatives are likely to also be appreciated.

Engagement with MyJourney was not as high as expected and it tended to decline over time. Low engagement with mobile/internet-based emotional support has been observed within fertility (e.g. van Dongen et al., 2016; Robertson et al., 2022a) and mental health care. Engagement tends to be lower when, as is the case with MyJourney, enrolment is entirely online, interventions are self-guided, long (>8 weeks), and do not target clinical populations (Linardon and Fuller-Tyszkiewicz, 2020). In addition to these factors, results indicate users' progression through Steps are a function of higher acceptability of MyJourney, ability to engage in acceptance journey, and lack of personal (e.g. work or other commitments) and technical (e.g. forgetting login details) barriers. Results also suggest that the time needed to progress through MyJourney varies across users and each specific Step being taken, with Steps involving orientation towards the future (e.g. values and goals clarification) being considered more challenging. This reflected in around half of users reporting needing more than a week to progress through each Step. Engagement findings may reflect the protracted nature of the adjustment process MyJourney targets, which is reported to unfold over a 2-year period (Daniluk, 2001). Alternatively, it may be that people need more time than expected to progress through self-guided web-based psychological interventions. For instance, infertile patients using a web-based mind-body programme who were invited to complete one of ten modules per week took around 3 weeks to complete each module (Clifton et al., 2016). Progression time may partially explain why overall the number of participants completing 6 (sufficient dose) and 10 Steps (full adherence) was low. However, it should also be noted that, on average, participants used MyJourney for 10 h. Assuming this corresponds to therapeutically structured time spent thinking about UPG adjustment, it certainly seems desirable considering the reported lack of access to formal support that motivated the development of MyJourney in the first place. In the future, it could be useful to evaluate if mental health professionals can use MyJourney to structure support provision for people with UPGs. Pairing the self-guided aspects of MyJourney with in-person support could help sustain engagement, by empowering people to engage in their acceptance journey in a regular way, potentially maximizing benefits.

A key finding is that MyJourney appears to be beneficial to users, producing improvements in joy and contentment (hedonic), and self-actualization and fulfilment (eudaimonic) that seem to remain stable for at least 6 months. The magnitude of these effects was moderate to large according to effect size indicators. Results also suggest a delayed improvement in mental health (depression, anxiety) and no changes in posttraumatic growth. The active component targeted in the first three Steps of MyJourney is acceptance of one's UPG (validation of experience, self-compassion, cognitive defusion). Given that around half of the participants who registered with MyJourney only completed these, it seems reasonable to propose that benefits result from higher acceptance. In previous modelling studies, the pursuit of new goals (Steps 4, 6 & 9) showed the strongest associations with outcomes (Gameiro, 2019), therefore it is reasonable to assume that with increased user adherence and/or progression benefits could be more holistic, as indeed observed in the 6-months follow-up. Overall results from limited efficacy testing indicate the 3TM is a valid therapeutic model to guide support provision for UPGs. Future support initiatives can draw on (and further evaluate) the 3TM and MyJourney's logic model to consider therapeutic targets to include.

Users found MyJourney acceptable due to being inclusive, appealing, user-friendly, and trustable, with the vast majority endorsing its use for others. As with other digital support (Robertson et al., 2022b), users appreciated the ability to use MyJourney in a flexible and autonomous way. However, not all users immediately recognized the significant benefits MyJourney triggered. Despite the favourable changes observed in hedonic and eudaimonic well-being, ratings on the usefulness of MyJourney and its Steps were halfway between moderately to very useful and, as noted, many users stopped engaging with it. These results warrant further examination. It could be these opposing results stem from two populations: those who benefit and those who do not. It could also be that benefits experienced are devalued by perceptions of the challenges still ahead which are reported to include a structural re-organization of one's life's central beliefs, priorities and social network (Daniluk, 2001; Gameiro and Finnigan, 2017; Koert and Daniluk, 2017). Finally, perceptions could relate to a sleeper effect whereby benefits take time to be noted (Park, 2010). Indeed, changes in mental health were only observed in the 6-months follow-up period (post acceptability assessment), and prospective research shows posttraumatic growth tends to take 10 months to happen (Daniluk, 2001). Making observed benefits more salient through MyJourney may help people to stay engaged with it. Future research focusing on MyJourney and UPGs need to consider a minimum follow-up period of 10 months to fully ascertain if holistic well-being gains are achievable.

In sum, acceptability and feasibility data and process evaluation indicate that MyJourney evaluation could proceed to a full RCT. Participants also considered the study protocol adequate and acceptable, including the randomization and questionnaire assessments. Attrition was driven by attrition in the intervention group and was slightly higher than expected when compared with other studies of e-health interventions within reproductive medicine. However, all these studies targeted people actively undergoing treatment, and included some level of researcher and/or health professional involvement throughout, while we opted for no researcher contact with participants to maximize ecological validity. This may explain observed differences in attritions rates. One solution is to deploy a 2:1 allocation (intervention: waitlist control) in the efficacy RCT.

Strengths and limitations

This was a pre-registered study with predefined progression criteria, theoretically driven by the Bowen et al. (2009) feasibility framework,

which facilitated a time- and cost-effective comprehensive evaluation of MyJourney and its efficacy study protocol. The study emulated real-world use of MyJourney (i.e. no researcher contact, unless triggered by the participant) and embedded a process evaluation, allowing for results validation via data triangulation. Evaluation of limited efficacy consisted of modified intention-to-treat and PPTs. Key limitations were that researchers and participants were not blinded to allocation and high attrition in the intervention group. Attrition resulted in low power to detect T2 to T3 changes in outcomes. In combination with self-reported questionnaire assessments, attrition could also have triggered bias favourable to positive evaluations of MyJourney. However, the high heterogeneity observed in participants' demand and acceptability ratings and in the process evaluation data suggests participants felt free to express both negative and positive views. Another limitation was that participants were a homogeneous group of white, well-educated, employed, childless women. Therefore, despite efforts to be inclusive (e.g. use of Prolific Academic research platform), which is reflected in heterogeneity in terms of UPG journey, it remains unclear if MyJourney is acceptable and useful to men, ethnic and other minority groups.

Implications

The development and evaluation of MyJourney is timely, considering population trends indicating an increase in the number of people living with UPGs and the striking absence of evidence-based (digital) support accessible to this population. MyJourney can proceed to efficacy testing, though future work should focus on eliminating technical barriers for engagement (e.g. enabling users to add a MyJourney icon to their phone and to remain logged in) and exploring strategies to maximize adherence (e.g. language, making MyJourney benefits more evident, maximizing interactive design). Technical and language barriers have already been addressed, and the team is exploring funding opportunities to address the remaining aspects. Meanwhile, MyJourney's benefits (free, easily accessible, positive impact on well-being, no unintended harms reported) seem to outweigh its limitations (moderate to high perceived usefulness, suboptimal user interface, low sustained engagement over time), justifying it being available for use. Fertility clinics can now meet requirements to provide tailored support for patients ending treatment (Gameiro *et al.*, 2015; HFEA, 2018) by signposting them to MyJourney. These patients, who usually express needing support and feeling abandoned by their clinics (Gameiro and Finnigan, 2017), can use MyJourney as a private and low-threshold support tool.

Conclusion

MyJourney fills a gap in the provision of evidence-based support for UPGs, but demand for support is high and more initiatives are desirable. This study highlights that such initiatives can be feasibly implemented online, acceptable and beneficial, triggering gratitude from those affected by UPGs.

Data availability

The assessment surveys and quantitative data underlying this study are available at https://osf.io/3avs5/.

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Authors' roles

S.G., B.R. and A.G. contributed to the conception and design of the study. All authors contributed to the acquisition, analysis and interpretation of the data. SG and BR drafted all versions of the article. All authors reviewed and approved the final version for publication.

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Conflict of interest

Dr S.G. reports consultancy fees from Ferring Pharmaceuticals A/S, speaker fees from Access Fertility, SONA-Pharm LLC, Meridiano Congress International and Gedeon Richter, grants from Merck Serono Ltd. Bethan Rowbottom holds a PhD scholarship funded by the School of Psychology, Cardiff University. The other authors have no conflicts of interest.

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