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ORIGINAL ARTICLE *Psychology and counselling*

Qualitative evaluation of the acceptability and feasibility among healthcare professionals and patients of an ART multi-cycle treatment planning and continuation intervention prototype

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STUDY QUESTION: Is it possible to design an ART Treatment Planning and Continuation Intervention (TPCI) that is considered acceptable and feasible to patients and healthcare professionals (HCPs)?

SUMMARY ANSWER: HCPs and patients responded positively to the TPCI prototype and perceived it as an acceptable intervention to support patients to stay engaged with planned treatment, but some concerns were raised about the feasibility of using it in practice.

WHAT IS KNOWN ALREADY: People discontinue ART due to its psychological burden. Digital tools to support people undergoing ART are available but typically focus only on practical support rather than psychological support. Research about treatment continuation and multi-cycle planning indicates that cognitive factors (expectations, intentions, efficacy beliefs) should be targets of interventions designed to help patients engage with and continue treatment to meet their personal treatment plans and goals. However, it is not known whether this form of psychological support would be acceptable for HCPs and patients or feasible to implement in practice.

STUDY DESIGN, SIZE, DURATION: Qualitative cognitive interviews with HCPs and patients (May 2021). Patients were eligible if they had had a consultation to start a first/repeat stimulated IVF/ICSI cycle in the 8 weeks prior to recruitment, were aged 18 or older (upper age limit of 42 years for women) and fluent in English. Eligible HCPs were those employed by a fertility clinic who were responsible for delivering treatment planning consultations to patients.

PARTICIPANTS/MATERIALS, SETTING, METHODS: HCPs and patients were asked to think aloud while being exposed to and exploring the TPCI in one-to-one online cognitive interviews. The TPCI was designed to reduce treatment discontinuation via cognitive factors namely formation and maintenance of multi-cycle ART intentions and efficiency of decision-making during treatment, and continuation of treatment after an unsuccessful cycle (when recommended). To impact cognitive factors the TPCI comprised of two components: an expectation management and reasoning checklist for HCPs to use during planning consultations (TPCI Checklist) and a multi-feature cognitive support mobile application (TPCI App) for patients to use prior to and during treatment. After participants thought aloud while being exposed to the TPCI prototype (both components) they were asked open questions concerning their perceptions of the core components and activities on eight acceptability dimensions (e.g. acceptability, demand, integration). Interviews lasted between 40 and 90 min, were recorded, transcribed verbatim and analysed using thematic analysis.

MAIN RESULTS AND THE ROLE OF CHANCE: Thirteen HCPs and 13 patients participated in 25 online interviews. Thematic analysis using inductive and deductive coding generated 180 codes, grouped into 22 categories and synthesized into 9 themes. The themes showed that HCPs and patients provided positive feedback about the TPCI, perceiving it as a needed, acceptable and potentially effective way to forewarn patients of the possible need for multiple cycles, to provide patients with a sense of patient–clinic collaboration and

support, and to bolster treatment intentions, all of which were perceived to contribute to reduced treatment discontinuation. HCPs perceived implementation of the TPCI Checklist to be challenging in its current length due to time pressures and clinic workload. Suggestions for enhancing the TPCI Checklist and App were provided, but none required critical changes to its core components or activities.

LIMITATIONS, REASONS FOR CAUTION: All patients were women recruited from social media websites, mainly associated with patient support groups, who may be highly committed to their fertility treatment. HCPs were predominantly from private fertility clinics.

WIDER IMPLICATIONS OF THE FINDINGS: The findings suggest there is demand for digital support geared towards motivational aspects of undergoing ART. The TPCI is an acceptable support tool to meet that need according to HCPs responsible for delivering planning consultations and patients undergoing fertility treatment. Future research is needed to develop the prototype and examine the feasibility of implementation of the TPCI in clinics.

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Introduction

People starting ART generally have good intentions to persist with treatment until they achieve their goal of parenthood and many people (>60%) attain parenthood if they do multiple cycles of ART (McLernon *et al.*, 2016). However, treatment intentions have been shown to get derailed in the face of adversity. Most people do only one or two complete cycles of ART even when funding is not an issue (Olsen *et al.*, 1998; De Neubourg *et al.*, 2021). About 22% discontinue treatment because they believe they cannot face the burden of another ART cycle or because they indefinitely postpone the decision to start another cycle (Gameiro *et al.*, 2012, 2013). Such distress or passive decision-making can lead to future regret (Chan *et al.* 2016). The present study investigates the perceived acceptability and feasibility to patients and healthcare professionals of a novel approach for addressing factors that derail treatment plans.

Research suggests that cognitive factors (expectations, intentions, efficacy beliefs) are critical to the pursuit of treatment. Systematic review shows that patients discontinuing treatment are those postponing decisions about re-engaging with treatment (Gameiro *et al.*, 2012). Decisional conflict impacts decisions but also mental health during treatment (Chan *et al.*, 2016). In contrast, patients continuing treatment after a failed cycle are those who expected to do multiple cycles prior to treatment engagement, had anticipated treatment decisions that might need to be made after a cycle failure (decision efficiency), and saw treatment failure as a learning opportunity and temporary setback they could overcome (Mesquita da Silva *et al.*, 2020; Burnette *et al.*, 2013). In previous cross-sectional research, patients and healthcare professionals reported three strategies to be important in reducing discontinuation (Harrison *et al.*, 2021, 2022). First, forewarning patients that the National Institute for Health and Care Excellence (NICE) guidelines recommend patients are offered up to three complete cycles of treatment (i.e. multiple cycles National Institute for Health and Care Excellence (NICE), 2013) to optimize cumulative chances of success. Second the importance of enhancing the sense of collaboration between patient and clinic. Third, the importance of supporting patients to anticipate and prepare for treatment challenges prior to treatment engagement (Harrison *et al.*, 2021, 2022). According to this research, adequate use of these strategies, alongside consideration of the patient's profile and professional recommendations, should support patients in making personalized treatment plans that are resilient when challenges (e.g. poor response, unsuccessful cycle) are encountered during the treatment journey.

These findings are consistent with theoretical work on the role of cognition in maintaining intention–behaviour links in the face of adversity (Gollwitzer, 1999). Of course, some patients may only undergo one cycle (i.e. due to affordability, preference, recommendation), but research suggests that for most patients, planning for multiple cycles from the start would optimize continuation (Mesquita da Silva *et al.*, 2020). Yet recent work suggests that people do not make plans, even when at high risk for treatment failure. For example, in a recent study of women 42–43 years of age with low probability of ART success (estimated <5% per cycle), almost 60% had no plans for the number of cycles they intended to do (Miron-Shatz *et al.*, 2021). Research also suggests there to be some anxiety about interventions directed at planning for multiple cycles among healthcare professionals (HCPs). Anxiety may be primarily due to the possibility of 'crushing optimism', being seen to work against patient preferences (e.g. to stop) or being exploitative, or as highlighting difficult realities (e.g. financial) of treatment (Harrison *et al.*, 2022).

The Treatment Planning and Continuation Intervention (TPCI) is a novel psychological intervention informed by theory and research evidence as well as user consultation (Harrison *et al.*, 2021, 2022). Figure 1 presents the TPCI logic model, which is an illustration of the (theoretically informed) causal logic of how the TPCI is expected to increase continuation of treatment, decrease time to pregnancy (i.e. the

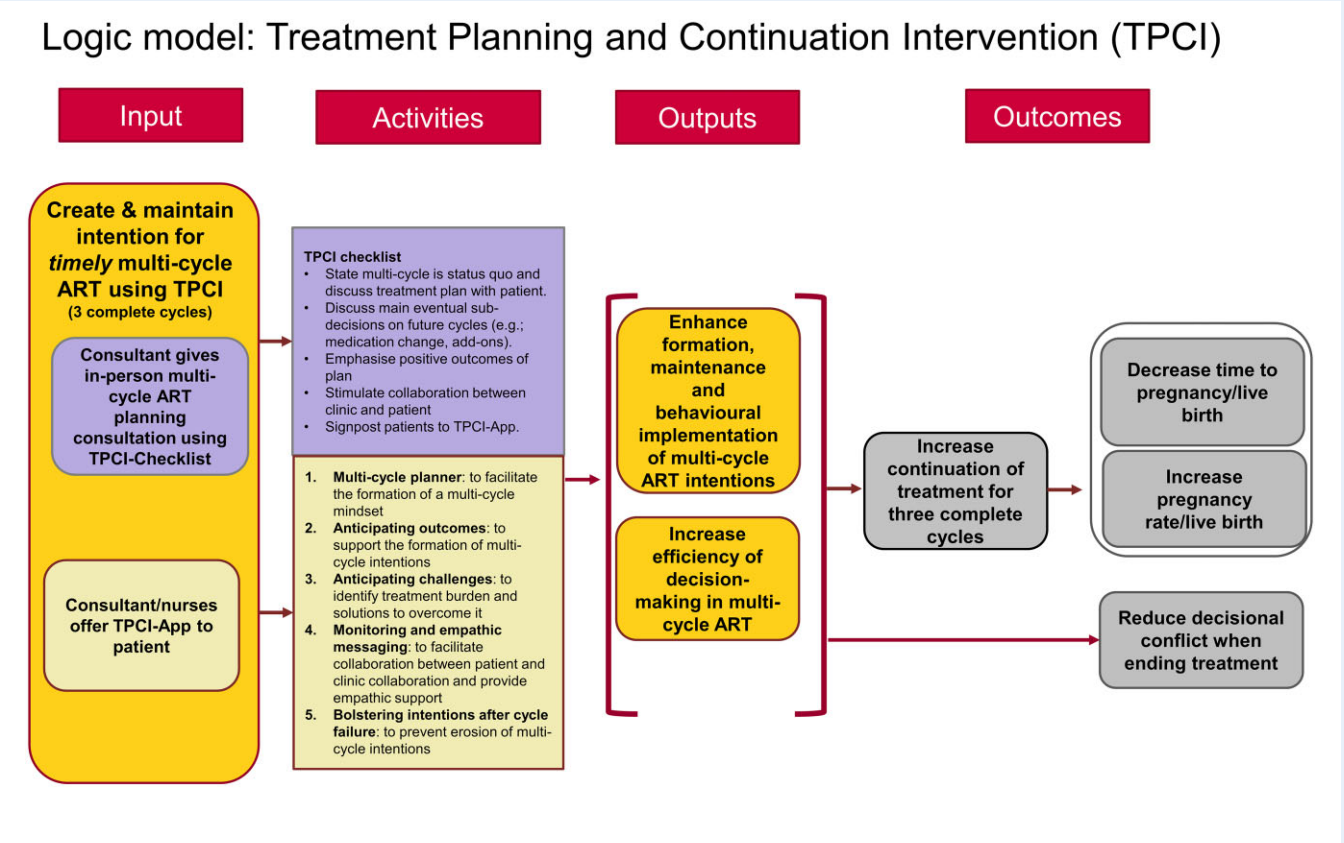

Figure 1. Treatment Planning and Continuation Intervention (TPCI) logic model.

time it takes to establish a pregnancy leading to live birth, measured in months or in numbers of treatment cycles; Zegers-Hochschild *et al.*, 2017; Sunkara *et al.*, 2020), increase pregnancy/live birth and reduce decisional conflict when ending treatment (TPCI outcomes). The TPCI is based on research supporting the value of generating informed treatment plans and expectations (i.e. forming strong intentions) and anticipating how to behave in the face of possible negative outcomes or challenges, to strengthen the link between intentions and behaviour implementation (Gollwitzer, 1999; Gollwitzer and Sheeran, 2006). It also incorporates user-requested features that were perceived to facilitate implementation of intentions, e.g. monitoring, and empathic messaging (Harrison *et al.*, 2022).

The TPCI logic model is supported by research evidence that suggests better cognitive preparation for the burden of treatment could help reduce treatment postponement and discontinuation (Harrison *et al.*, 2021, 2022). Cognitive preparation is targeted by doing multi-cycle planning and all the TPCI activities included in the checklist and app support this endeavour. By multi-cycle planning is meant that from the start of treatment, consultations with patients include acknowledging the high likelihood of cycle failure, presenting the benefits of undergoing multiple cycles (i.e. three complete cycles of treatment) to maximize the chance of success *and* planning from the start to do multiple cycles (Harrison *et al.*, 2021, 2022). All this is discussed in the context of acknowledgement of, and support for, overcoming the challenges of undergoing multiple cycles. Multi-cycle planning therefore implies anticipating the decisions that may need to be made across the course of treatment. These include, preparing and identifying solutions for the typical challenges experienced during treatment, fostering HCP-patient collaborative and empathic relations during treatment, avoiding derailing intentions, and signposting patients to other sources of support if planned treatment ends without successful outcome. Patients should also be signposted to other sources of support if they are unable to plan for and undergo multiple cycles (e.g. financially unable to afford multiple cycles). Multi-cycle planning is proposed to work by enhancing formation, and behavioural implementation, of multi-cycle intentions, and to increase efficiency of decision-making during treatment (See Figure 1 and TPCI outputs; Harrison *et al.*, 2021, 2022). These are, in turn, expected to increase continuation (Bhattacharya *et al.*, 2021), leading to higher live birth rates and shorter time to pregnancy, as well as lower decisional conflict between cycles, or when ending treatment.

There are several digital patient support interventions reviewed in the support literature, but these tend not to be specific to ART, to focus on administrative and practical support (Robertson *et al.*, 2021) or, if focused on ART, then tend to be concerned with tracking medication or reducing emotional impacts via the promotion of patient centred care and adaptive coping (Huppelschoten *et al.*, 2015; Meyers and Domar, 2021; Robertson *et al.*, 2022). The reviews highlight an absence of psychological interventions that provide patients with resources to support them in defining a personal treatment plan and

maintaining strong intentions that translate in actual implementation of their plan (Domar *et al.*, 2019; Meyers and Domar, 2021). Qualitative research indicates that patients seeking treatment and HCPs providing fertility care identify cognitive support as helpful (Harrison *et al.*, 2022) but it is not yet known whether an intervention designed to support a treatment mindset would be considered acceptable and feasible to use as part of routine clinical practice. The aim of the present study was therefore to address this gap in patient support by examining in patients and HCPs the perceived acceptability and feasibility of the TPCI. We assessed eight dimensions of acceptability that according to Bowen *et al.* (2009) should be targeted to determine whether an intervention is appropriate for further efficacy testing or implementation: acceptability, demand, implementation needs, practicality, adaption, integration, expansion and limited-efficacy testing.

Materials and methods

Participants

Eligible HCPs were those employed by a fertility clinic, who delivered treatment planning consultations to patients. Patients were eligible to participate if they had a consultation to start a first or repeat stimulated cycle of IVF/ICSI within 8 weeks prior to recruitment, had not previously had more than two stimulated cycles of treatment, were aged 18 or older and able to respond in English. The upper age limit of 42 years for women was applied due to limit for publicly funded fertility treatment in the UK (Human Fertilisation and Embryology Authority (HFEA), 2019). Patients were excluded if they had been advised to stop IVF/ICSI, had more than two complete cycles or if their most recent consultation (i.e. within the previous 8 weeks) was for a frozen embryo transfer. Complete cycles were defined as all embryo transfers (including frozen) resulting from one episode of ovarian stimulation. To focus on typical ART, participants were also excluded if they had undergone IVF/ICSI for pre-implementation genetic diagnosis because of a genetic disorder, fertility preservation, surrogacy or were using donated gametes (egg or sperm). Participating patients (but not HCPs) were offered £20 as a reimbursement of their time. All data were collected during May 2021.

Materials

The Treatment Planning and Continuation Intervention

The TPCI prototype is based on research evidence indicating that addressing cognitive factors during treatment planning could support patients manage the burden of treatment during multi-cycle treatment (Boivin *et al.*, 2012; Gameiro *et al.*, 2012; Mesquita da Silva *et al.*, 2020; Harrison *et al.*, 2022). Figure 1 presents the TPCI logic model, which is an illustration of the theory and causal logic of how the TPCI achieves its aims (for more information on the use of logic models see McLaughlin and Jordan, 1999). The logic model was informed by theory (e.g. Gollwitzer and Sheeran, 2006), the integrated model of fertility care (Boivin, *et al.* 2012), systematic reviews on treatment compliance (Gameiro *et al.*, 2012, Gameiro *et al.*, 2013) and empirical cross-sectional studies about planning for multi-cycle ART treatment (Harrison *et al.*, 2021, 2022). Subsequent rapid reviews on intention–implementation, expectation management, advanced decision-making and empathic relationship (unpublished) were conducted to inform the design of the intervention and intervention activities considered necessary to trigger the hypothesized outputs. According to the TPCI logic model, promoting treatment continuation requires the creation, maintenance and implementation of timely multi-cycle ART intentions which is achieved via two components in the TPCI (see Fig. 1). First, an expectation and reasoning checklist for HCPs (TPCI Checklist) comprising six main points, to manage patient expectations and support the formation and maintenance of multi-cycle ART intentions, without crushing patient positivity and treatment optimism. Second, a patient support mobile phone application (TPCI App) with five embedded activities designed to reinforce expectation management and support multi-cycle intentions and implementation, namely: multi-cycle planning, anticipating outcomes, anticipating challenges, monitoring and empathic messaging, and bolstering intentions after cycle failure (see Table I for more detail on activities). These components and activities were informed by previous research (Harrison *et al.*, 2022) and designed to create two outputs (i.e. mechanisms of action), namely the enhancement, maintenance and behavioural implementation of strong multi-cycle treatment intentions and increased efficiency of decision-making. These mechanisms should lead to increased continuation of treatment after an unsuccessful cycle (when recommended) and reduced decisional conflict between treatment cycles and when ending treatment. We hypothesize this will result in better outcomes for patients: shorter time to pregnancy/live birth and increased pregnancy/live birth rate.

Cognitive interviews and think aloud task

HCPs and patients were exposed to a digital interactive prototype of the TPCI. The two components of the TPCI (i.e. checklist and app) were presented as they might be delivered to HCPs and patients if they were to become part of routine clinical practice. This is a pseudo app without any working code or final design elements focused on the essential, innovative and most highly relevant app features (i.e. main user interfaces, screens) with simulations of how the app would work. Participants could go through the TPCI app as if real, touching buttons adding names etc. to simulate the app. HCPs and patients were first asked to communicate aloud and continuously report their thoughts and feelings while navigating and using the TPCI prototype according to the Think Aloud technique (Ericsson and Simon, 1999). During verbal streaming, the researcher could ask questions to clarify and capture insight into the usability of the TPCI and its interface (e.g. level of understanding, sense checking). Following exposure to the TPCI HCPs and patients were asked 22 open questions (including prompts) to further probe their views of the TPCI. The questions were framed according to Bowen *et al.*'s (2009) acceptability and feasibility framework that determines whether an intervention is appropriate for further testing (e.g. efficacy testing). As such, appropriate areas of focus for questions were made along eight dimensions (i.e. acceptability, demand, implementation, practicality, adaption, integration, expansion and limited efficacy). Open questions about the TPCIs acceptability and feasibility concerned the TPCI prototype as an intervention (i.e. checklist and app), the checklist and app as separate components, and the individual components and activities of the app.

Table I Summary of the Treatment Planning and Continuation Intervention (TPCI) prototype's two core components and activities.

TPCI component	TPCI activities
TPCI Checklist (Healthcare Professionals (HCPs))	
Expectation management and reasoning: to manage expectations and facilitate the formation of a multi-cycle mindset	HCPs use the TPCI Checklist at the start of treatment (i.e. during planning consultation). The TPCI Checklist covers six main points to support formation of multi-cycle expectations without crushing positivity: (i) informing patients about the likely need for multiple cycles; (ii) defining chances of success with up to three complete cycles of treatment following NICE guidance; (iii) informing patients about possible treatment outcomes and options; (iv) understanding patients planned number of cycles; (v) presenting treatment as a collaborative endeavour between patient and clinic; and (vi) introducing and signposting patients to the TPCI app. HCPs can revisit the checklist before meeting patients for repeat consultation when treatment has been unsuccessful.
TPCI App (Patient)	
1. Multi-cycle planner: to facilitate the formation of a multi-cycle mindset	Patients use this activity to record their prior treatment experience and personal plan for the number of cycles they are willing to do (i.e. intention formation). It supports patients to form a multi-cycle personal plan at the start of treatment. Patients can revisit this plan throughout the treatment journey and when their treatment journey is not successful.
2. Anticipating outcomes: to support the formation of multi-cycle intentions	Patients use this activity to learn common treatment outcomes at each stage of the ART process (e.g. stimulation, oocyte retrieval) in advance of treatment. Patients are also asked to consider their preferences should they face protocol changes. Patients first use this activity in advance of treatment, at a time that is typically less emotionally charged than when a negative outcome has occurred but can revisit it throughout the treatment journey.
3. Anticipating challenges: to identify treatment burden and solutions to overcome it	Patients use this activity to plan overcoming challenges in advance of treatment. The activity comprises an eight item Problem-Solution matrix based on common challenges and patient reported solutions experienced when doing multiple cycles of treatment. The activity can be revisited throughout the treatment journey.
4. Monitoring and empathic messaging: to facilitate patient-clinic collaboration and provide empathic support	Patients use this activity to record their treatment stage (e.g. stimulation, retrieval), journal their emotional and physical reactions to treatment using a well validated daily record keeping form for ART and record their reactions to treatment (e.g. number of follicles developing) according to own preferences. These activities are used to prompt the delivery of psychologically informed empathic messages at key moments during the treatment journey in a balanced way and according to patient preferences. Patients can use this feature throughout their treatment Journey.
5. Bolstering intentions after cycle failure: to maintain multi-cycle intentions according to personal plan	Patient reporting of a failed cycle triggers the app to deliver empathic message and invite patient to revisit their initial multi-cycle treatment plan (Multi-Cycle Planner) and arrange a follow up appointment.

Procedure

The ethics committee at the School of Psychology, Cardiff University provided ethical review and approval for the study (EC.21.02.09.6297). HCPs and patients were recruited via Facebook and Instagram with the assistance of patient charities (e.g. Fertility Network UK), social influencers and fertility clinics, with adverts asking people to e-mail the researchers if they were interested in participating in an interview about a treatment planning intervention that was being developed. Those interested were sent more information about the study (including inclusion/exclusion criteria) and a consent form. Those eligible to participate who consented were allocated to a cognitive interview date based on their availability. Each cognitive interview started with the researcher (CH) providing more information about the aims of study, procedure for the interview, a set of ground rules (e.g. confidentiality, feeling free to express opinions even if negative, no right or wrong answers) and a reminder of video recording, as per consent. The interviewer (CH) shared the screenshots of the TPCI Checklist with participants and asked them to think aloud as they processed the information presented. Participants were then sent a link to the prototype of the TPCI App, which was clickable, and instructed to share their screen with the interviewer. Participants were instructed to navigate their way through the app thinking aloud as they did so. The interviewer navigated through the app for individuals who were technically unable to share their screen due to the device they were using but this navigation was verbally directed by the participants. The procedure was the same for HCPs and patients. At the end of the interview, participants were thanked and sent a link with more information about the study. HCPs and patients were exposed to both the checklist and the app to gather data on acceptability and feasibility for the population that would hypothetically use the TPCI if it were to be implemented and become part of reproductive care. By showing the checklist to patients as well as HCPs we aimed to capture patients' perceptions about how they would feel receiving such a consultation. By showing the TPCI app to HCPs we aimed to capture data to ensure the design and concepts would be supported by HCPs, as ultimately, if implemented within clinics, HCPs would have to introduce the app to patients as part of the multi-cycle consultation.

Data management and analysis

Each interview recording was transcribed verbatim and imported into NVivo version 12 (QSR International, 1999). Data were analysed using thematic analysis according to the method of Braun and Clarke (2006) with the first steps being transcription and familiarization with data (listening back to audio-recorded interviews and re-reading each transcript). Inductive coding was then used to attach meaningful labels to textual data and generate initial codes. Coding was carried out until no new codes (variation in data) were identified (theoretical saturation reached). Codes were linked to specific intervention component (e.g. Checklist, App activities) and interview question, where occurring. Categories were then further deduced to themes that captured Bowen *et al.*'s (2009) acceptability framework. Themes were cross-checked against extracts of data. Textual data analysis was presented as a summary accompanied by illustrative verbatim quotations. Within illustrative quotations, the use of [. . .] indicated part of the quotation was not presented because it was not relevant whereas (text) indicated additional text was added for clarity (i.e. readability, comprehensibility). Grammatical errors were corrected and idioms ('like', 'you know', 'kind of') removed. Verbatim quotations were labelled according to whether they were from an HCP or patient (P) and accompanied by a participant number.

Results

Recruitment outcome

A total of 25 interviews (24 interviews with single participants, and 1 interview with 2 participants) were conducted, 11 interviews with consultants, 1 with a nurse and 13 with patients. Most consultants were from private fertility clinics ($n = 10$), male ($n = 8$), and one consultant was accompanied by an embryologist colleague during the interview. All patients were female, with a mean age of 33.23 ($SD = 4.55$), childless, in heterosexual relationships, had been trying to conceive for ~3 years ($M = 2.46$, $SD = 1.05$) and had on average one previous cycle of treatment ($M = 1.40$, $SD = 0.55$). Interviews lasted between 45 min and 1 h 30 min depending on HCP and patient availability.

Thematic analysis

Thematic analysis produced a total of 180 codes that were grouped into 22 categories linked to intervention component (TPCI Checklist and App) and interview questions. These produced nine themes that were mapped onto Bowen *et al.* (2009) acceptability framework questions. From the 180 codes, 19 pertaining to suggested amendments to the TPCI's interface, layout or design and use of language could not be deduced into the Bowen *et al.* (2009) framework so they formed a separate additional theme. All the themes and categories emerged for both patients and HCPs; however, several codes were exclusive, only being referred to by either patients or HCPs. Table II provides a summary of the findings arranged according to deductive and inductive theme with illustrative verbatim quotes.

Acceptability and demand

Overall, participants provided positive feedback about the TPCI. Patients and HCPs perceived the TPCI to have value in terms of content and novelty. One HCP reported it to be a radical change to planning consultations but perceived benefits in the multi-cycle planning approach.

Both patients and HCPs perceived there to be many benefits of the TPCI, for themselves and the clinic. Perceived benefits include, increasing the amount and reliability of information available to patients, the consistency of information received from different information sources and the formation of realistic expectations. This was linked to patient and HCP expressions of interest in using the TPCI because the potential for the TPCI to provide in-depth, higher-quality information was attractive. As such, the TPCI was perceived to be needed by most HCPs and patients with many expressing an immediate desire for its use. Moreover, the use of the TPCI in clinics across the UK was welcomed and perceived to bring another element of consistency to patient support and care.

The patients ($n = 2$) who were less likely to express a desire to use the TPCI App were those who felt a personal need to leave treatment at the clinic or did not see themselves using an app as a support tool. Nevertheless, these non-users saw benefits in the app for other patients.

Some ambivalence was expressed in terms of the feel and perceived appropriateness of the TPCI. For example, one patient reported apps, and thus the TPCI App, felt formulaic and unnatural as support tools. Patients and HCPs also expressed some concern regarding unintended effects. First, was concern about delivering a multi-cycle planning consultation when individuals did not have the option of doing multiple cycles because of financial reasons. In these cases, the TPCI Checklist and App could trigger negative effects. Second was the possibility of patient exploitation and possible financial motives of multi-cycle planning. Delivering a multi-cycle consultation could result in patients feeling pressured into doing more treatment than desired. Finally, multi-cycle planning was perceived to frame ART negatively from the outset, discouraging treatment optimism and hope, or making patients feel disheartened about their chances of achieving a pregnancy and live birth.

Implementation and practicality

A source of hesitation was the implementation and practicality of the TPCI Checklist, which was perceived to be too detailed to be implemented in the amount of time HCPs have to plan treatment with patients. Some HCPs suggested that counsellors could be involved with the implementation of the TPCI Checklist to share time burden because some of the content of the checklist was perceived to go beyond their role of treatment decision-making and planning.

Implementation of the TPCI App was perceived to be straightforward requiring no major resources. However, HCPs expressed concern that the claims made within the app (e.g. help you persevere with your treatment plans) needed to be better evidenced prior to implementation. For example, providing evidence that using the app helps patients persevere with treatment was suggested to increase the likelihood of patients and HCPs endorsing and adopting the TPCI and thus the multi-cycle approach to planning. HCPs suggested the revision of such claims. In addition, it was proposed that patients be made aware that the TPCI was independently developed by academics to minimize any patient mistrust. For example, one HCP reported the importance of separating the TPCI from the clinic to avoid multi-cycle planning being associated with financial motives for the clinic.

Table II Mapped deductive[1] themes, inductive themes and illustrative quotations from patients and healthcare professionals (HCPs).

Mapped deductive themes	Inductive themes = Nr of codes within category	Illustrative quotations
Acceptability The extent to which the Treatment Planning and Continuation Intervention (TPCI) is judged as suitable, satisfying, or attractive to patients and HCPs	**Perceived high value of TPCI and its activities** 14 codes within category	'[The] concept of the app is really great. I think that there is lots of things in there that are reassuring and that would really support someone in their treatment planning' (Patient, P17). 'So as a whole [. . .] I've never seen anything like it, so it's quite radical, and it's [. . .] impressive, it's pretty good [. . .] it brings planning and care into the centre of the consultation' (HCP, P11).
	Perceived benefits of TPCI and its specific activities including managing expectations and maintaining treatment optimism and hope. 19 codes within category	'I like the [overcoming] challenges tab. I thought that was good—not good, useful. That would be useful' (Patient, P15). 'I think that (the information in the checklist) is really a good thing to do to manage patient expectations' (HCP, P7).
	TPCI provides accessible reliable information 6 codes within category	'If they (clinic) can give you virtual support, which is what they actually say is happening to you or what you would do in a certain situation, then obviously that would reassure you, wouldn't it? Because there is so many things that you can read on the internet and sometimes, they can scare you' (Patient, P16). 'But I think as long as there's consistency (between TPCI and clinic information), that's what we need above and beyond anything else is consistency of information' (HCP, P12).
	Ambivalence about appropriateness of intervention and activities 8 codes within category	'I could see the benefit of you exploring your options and, your own preferences, but at the same time, you are making plans for things that possibly aren't even on the cards, ever. I do not know how helpful that might be and it just depends on what kind of frame of mind you are in at the time as well' (Patient, P14). 'They can read about it but until you are in the hospital and you are getting [. . .] OHSS [. . .] asking them to make a plan about [. . .] what would you do if you had OHSS? It is a bit premature' (HCP, P4).
	Association with multi-cycle packages causes mistrust in multi-cycle approach 9 codes within category	'It just makes me think that you have already decided that you are going to need more cycles and now you're priming me to accept that' (HCP, P7). 'The cynics amongst us will say that actually all you're doing is convincing patients to come with the mindset that they want to pay for three treatments rather than one' (HCP, P3).
	Perceived negatives from the intervention, including false hope and treatment pessimism 5 codes within category	'They [patients] might just feel that: well, that means that I'm not going to be successful in my first cycle, and that's because it's under the NHS and my free round and the clinic probably wants me to spend more money' (HCP, P7). 'If they [HCPs] would have said I had to have three cycles to do this, I do not know how I would feel. I would probably be a bit gutted, a bit disheartened' (Patient, P16).
Demand The extent to which TPCI is likely to be used (i.e., how much demand is likely to exist).	**Expressed interest, intention to use or perceived demand for the TPCI** 9 codes within category	'I'd definitely download it, and use it' (Patient, P22). 'Would we know when your checklist and apps will be ready for us to use' (HCP, P6). 'I just feel like once I had left the clinic, I try and switch off from everything [. . .] I can't imagine getting home, sitting down and recording it all' (P15, Patient). 'It is helpful. I am just not sure if I would personally use an app' (Patient, P14).
Implementation The extent, likelihood, and manner the TPCI could be delivered to intended participants as planned and proposed	**Degree of execution of the TPCI as planned and proposed and perception of resources needed for implementation** 10 codes within category	'[Patients would] need to understand that [TPCI] is not coming from the doctor who's trying to convince us and [to] keep getting our money. But [TPCI] is actually [based on] valid research and the doctor is referring us [. . .] because the doctor cares about us and about our emotional wellbeing' (HCP, P4). 'If the clinic is suggesting it, then that suggests that they're on board with it and they may want to review it with you' (Patient, P21). 'It is a good idea. [. . .], the trouble will always be in the implementation. [. . .] unless people are sort of sold on the idea that it (the checklist) is worthwhile for them, I am talking about health care professionals, it would be quite incredibly challenging' (HCP, P8). 'The clinic counsellor should certainly be part of presenting this to [patients]' (HCP, P11). 'Time is a big issue here [to using the Checklist]' (HCP, P5).

(continued)

Table II Continued

Mapped deductive themes	Inductive themes = Nr of codes within category	Illustrative quotations
Practicality The extent to which the TPCI could be carried out with intended participants using existing means, resources, and circumstances.	**Previous treatment experience and level of treatment knowledge could impact use of TPCI activities** 2 codes within category	'Because I just do not feel like I know enough [. . .] about it to make I suppose a clinical decision about it [treatment outcomes and protocol changes]' (Patient, P14). 'If [. . .] I was in my first cycle, that could be quite intimidating for me as well, because it's new information' (Patient, P16).
	Positives effect of implementation of TPCI on participants and organization including anticipating treatment challenges and decisions, addressing psychological and emotional needs and treatment transparency 14 codes within category	'So sometimes it can be quite dangerous to set people up to believe that multiple treatments can overcome a major problem which is failure to response to stimulation medication, we've got to keep that door open as well' (HCP, P3). 'Probably would be able to take pressure off the clinic a little bit as well. because I know that they do get lots of phone calls with just little things' (Patient, P25).
	Negative effect of implementation of the TPCI on participants and organization, including, triggering information, unnecessary stress and obsessive treatment preoccupation 7 codes within category	'[Patients] could also use this app to become very, very over focused on what is all happening' (HCP, P5). 'A lot of people could probably get quite lost in it. They probably get a bit obsessed with it' (Patient, P25).
	Design and presentation of information is linked to participants ability (and desire) to use TPCI and carry out TPCI activities 6 codes within category	'It is quite plain, at the moment. If there was some way of making it a little bit more [. . .] engaging to the eye' (Patient, P24). 'This does not look like a checklist. It looks like an information sheet, or like a leaflet or pamphlet' (HCP, P4).
Adaption To what extent could the TPCI perform, when changes are made for new format or with a different population	**Perceived inclusivity of the TPCI and suggested amendments to make TPCI applicable to different populations (e.g. partners, single people) and individual needs (e.g. education level)** 12 codes within category	'A lot of young people would hate to read. Young people. They stop immediately if they have to read. And that is very unlike my generation. So, I suggest. I suggest a cartoon that talks to you' (HCP, P2). '. . . if you could have the app connected between the two partners so they could view what each [. . .] was thinking' (Patient, P17).
Integration The level of system change that may be needed to integrate the TPCI into clinical practice	**Perceived fit of TPCI to current clinical practice, including cultural change, and sustainability of the TPCI** 6 codes within category	'So, I think it is quite radical. I think it will mean changing the style of consultation. I think some clinicians will find it difficult [. . .] I think it will need quite a lot of people to change the way they do their consults' (HCP, P11).
	Perceived need for consistency of information and terminology between clinic and TPCI 13 codes within category	'I think as long as there was a degree of overlap with the information that is linked to electronic consents' (HCP, 12). 'I can imagine a conversation where the patient says, well, I checked on the app and I made a plan I want to have two embryos next time, and the doctor said, well, that's not available to you and then you get into a conversation that that ends up diminishing the value of the app' (HCP, P11).
Expansion To what extent could the TPCI be expanded to provide a new program or service?	**Suggested additions to expand the services and support the TPCI can provide to patients and the clinic** 2 codes within category	'I think, if (the TPCI App) had the ability to then take you into a community room, chat room or message board about some of the things. I think I would find it better to be able to engage with others through the app as well' (Patient, P22). 'Is there any way where they can get in touch with other people who are using the same app. To get some support' (HCP, P7).

(continued)

Table II Continued

Mapped deductive themes	Inductive themes = Nr of codes within category	Illustrative quotations
Limited efficacy Does the TPCI show promise of being successful in achieving its activities and outputs?	**Perceptions the TPCI forewarns patients about the possible need for more than one cycle of treatment** 2 codes within category	'We don't always make it a point to look to discuss this [possible treatment outcomes and options] before they start their treatment, so I think it is useful (for) the patients to (be) aware of this at the beginning of the treatment and feel more supported as part of their journey' (HCP, P7). 'I think it is quite effective. I think I would have really benefited from it, in terms of being realistic and that it is OK to do more than one cycle. It is the norm' (Patient, P17).
	Perceptions the TPCI fosters a sense of collaboration and support between the patient and the clinic 12 codes within category	'Completely agree that's [presenting treatment as a collaborative journey between patient and clinic?] very, very important. Patients should have trusts in us, and we should have trust in our patients' (HCP, P6). 'I think it shows a bit more of commitment to you as a patient that they want to help you through the whole process from start to finish' (Patient, P24).
	Perceptions the TPCI bolsters treatment intentions throughout treatment and after an unsuccessful cycle 4 codes within category	'Yeah, really important, to go back and look at your goals and make sure that what's happening at that moment in time isn't [. . .] impacting the original goal that you had' (Patient, 13). 'It's good [. . .] this is to remind you what you had selected when you, or what you had an indicated when you started the journey' (HCP, P4). 'This pop up saying that its normal and you can consult with your doctor and go forward and revisit your plans, sort of giving you a boost to go forward rather than regress and make yourself feel worse' (Patient, P25).
	Perceptions the TPCI promotes patient empowerment and control 2 codes within category	'I feel like (the TPCI) would enhance your experience and your sense of agency and decision making with your doctor' (Patient, P17). 'it gives patients a sense of ownership over their treatment cycle [. . .] because your intentions for your cycle' (Patient, P21). 'It's (TPCI app) good for feeling like you are in control' (Patient, P22).
Limited efficacy Does the TPCI show promise of being successful in achieving its outcomes?	**Perceived efficacy of the TPCI for promoting treatment re-engagement** 1 code within category	'I think you would probably see, a difference [. . .] you would probably see a difference in continuation rates. Uhm and if you had some measure of control, the feeling of control or the feeling of anxiety, then I think you might notice differences in that' (HCP, P11). 'For example, when I tick that box saying unsuccessful (that) pop up saying that its normal and you [. . .] can consult with your doctor and go forward and revisit your plans, (gives) you a boost to go forward rather than sort of regress and make yourself feel worse' (Patient, P25). 'Yes, yes, quite simply, I think yes' (HCP, P11).
Other theme—TPCI Improvements Suggested improvements to the TPCI to enhance its acceptability, practicality, and implementation.	**Suggested amendments to style and wording of checklist and app to improve the acceptability and feasibility of the TPCI** 19 codes within category	'I mean, you've got to be careful whether you want to use the word patients or people' (HCP, P3). 'So, it (the checklist) has to be short, brief and essentially, it can be completed within 5 minutes' (HCP, P4). 'It's a bit dry the layout. It would be good if it was supported by charts, graphics' (HCP, P4). 'It's quite long winded and wordy really. If I was on an app like this, I would want to get to the bits that actually help me' (Patient, P15).

[1]Deductive themes and definitions according to Bowen *et al.* (2009).

Practical issues surrounding the implementation of the TPCI included concern that patients with little or no previous treatment experience would lack the required knowledge about treatment procedures, options, and protocol changes to use the TPCI and its activities effectively. A couple of HCPs and patients reported that the implementation of the TPCI may be easier, more beneficial and engaged with differently after patients had completed at least one cycle of treatment.

Implementation of the TPCI was perceived to have benefits for patients and the clinic. The TPCI was perceived to provide a patient-centred approach to treatment planning. One patient also reported that the TPCI App could ease workload pressures for the clinic by providing patients with a trustworthy tool incorporating evidence-based resources that could reduce the number and frequency of patients contacting the clinic. However, there was concern that implementation of some activities of the TPCI App would result in patients becoming too focused on their treatment and that some language could be perceived as disrespectful or have a negative effect for some patients. HCPs stressed the importance of the patient remaining the focus of attention after the implementation of the TPCI.

Adaptation, integration and expansion

The design and inclusivity of the TPCI were also considered. Patients and HCPs were able to suggest amendments to ensure the TPCI App was applicable to all users (e.g. single people, partners, non-English speakers). For example, HCPs reported the TPCI activities could perform better for younger individuals if they incorporated features reflecting current user preferences for digital tools (e.g. voice memos, animations).

Because current norms in clinics are for cycle-by-cycle planning, integration of the TPCI was perceived to require a culture change for clinics and HCPs in terms of how they planned treatment with patients. Some HCPs felt this culture change could pose a significant challenge, especially for more experienced clinicians. For new HCPs, integration of the TPCI Checklist was not perceived to be as challenging because it could be the norm from the outset of their clinical practice.

To ensure the successful implementation and integration of the TPCI into clinical practice, HCPs highlighted the need for consistency and clarity in information provision and terminology (e.g. success rates, cycle of treatment definition) between the TPCI and the clinic to avoid creating misunderstanding or the app devaluing what the clinic says and vice versa.

While the TPCI core components and activities were overall perceived to be acceptable and comprehensive in their current format suggestions were made to expand the TPCI's provision of services and support. For example, patients highlighted the added value that a chat room or community space could add to the app. Patients reported that this would encourage patients to feel part of a community, with access to learn and gain support from other people in similar situations with similar experiences. Other suggestions to expand the provision of services for patients and the clinic included enabling direct communication between the app and the clinic so that, for example, the HCPs could view preferences patients express within it, prepare for patient appointments, and respond to patients in a timely manner while also acknowledging and keeping track of their physical and psychological needs throughout the treatment journey.

Perceptions of efficacy

The TPCI was perceived by HCPs and patients to achieve its activity aims of forewarning patients about the possibility of needing more than one cycle, encouraging a sense of collaboration and support between clinic and patient, and supporting patients to re-engage in treatment after an unsuccessful cycle by revisiting, and thus bolstering, their initial treatment intentions. As such, the TPCI was perceived to promote the formation and maintenance of multi-cycle ART intentions and treatment decision-making efficacy. Patients and HCPs perceived the TPCI to help the formation of realistic treatment expectations and thus the high possibility of needing to engage in more than one cycle of treatment. Being forewarned about the possible need for more than one cycle of treatment was also seen to help reduce the amount of pressure patients often put on themselves for the first cycle of treatment to be successful.

The TPCI and its specific activities were perceived to encourage a sense of collaboration and support between the patient and the clinic. For example, being equipped with the information provided in the app was reported to enable patients to initiate discussions with HCPs, giving them more confidence to ask questions. The TPCI app was also perceived to be an important source of support, particularly when treatment failed. Patients reported the provision of empathic messages and the prompt to revisit their initial treatment intentions, to re-instil a sense of treatment optimism and hope. Nonetheless, they also noted that the act of self-reporting their treatment to be unsuccessful on the app could be a challenge.

The TPCI was also perceived to be an important addition to patient care for encouraging patient autonomy, specifically for empowerment and sense of treatment control. Patients and HCPs reported that the TPCI could be empowering for patients, increasing their sense of involvement and control over their treatment. These perceived benefits were largely due to being able to input personal treatment data about how the treatment was progressing (e.g. number of developing follicles) and being able to anticipate possible treatment decisions and protocol changes. Overall, participants reported that the TPCI components and activities could be effective for reducing treatment discontinuation. There was, however, a general agreement among HCPs for the need for more research to evaluate outcome effectiveness with many suggesting the employment of a randomized controlled trial.

TPCI improvements

Suggestions for improvements covered four aspects: comments related to the style and wording used in the prototype to improve its sensitivity and acceptability (e.g. using failure versus unsuccessful, patient versus people, planning versus preference, many versus most); design issues about how best to optimize content, delivery and use among the intended intervention recipients; design aspects to aid use of the activities; and some suggestions were made about how to reduce the content of the app to aid patient engagement throughout treatment.

Discussion

Results indicate that it is possible to design an ART TPCI that is acceptable to patients and HCPs and that there is demand for such an intervention within the UK. HCPs and patients provided positive feedback about the overall concept, two core components (TPCI

Checklist and App) and associated activities of the TPCI, perceiving the TPCI as a needed, acceptable and effective way to help patients engage with ART treatment. Nonetheless, some ambivalence was expressed due to implementation issues for the TPCI checklist, mistrust in multi-cycle planning, potential negative effects of multi-cycle planning for patients with limited financial resources, and design issues related to sensitivity, acceptability and adaption to other populations doing ART (e.g. single people, partners, LGBT+ communities). Results validate the need and value of patient support designed to promote cognitive factors that clarify and sustain patient treatment intentions through the challenges of ART. Altogether the results indicated the TPCI can meet the eight dimensions of acceptability and feasibility defined by Bowen et al. (2009). The next steps for the development of the TPCI would be to build the TPCI and carry out further feasibility testing using a cluster randomized control trial design with integrated process evaluation and assessment of outcomes specified in its logic model.

Overall, there was agreement that the TPCI showed potential to trigger the mechanisms of change of enhancing the formation and maintenance of multi-cycle ART intentions and efficiency of treatment decision-making during treatment, all of which were valued by participants. HCPs and patients expressed that the TPCI could help clinics provide patients with in-depth, structured and consistent information about what to expect from ART. Such information could help HCPs set, and patients form, realistic treatment expectations (e.g. IVF as a potential multi-cycle treatment, potential challenges and decision points) while also preserving treatment optimism, which has been shown to be important for patients initiating treatment, and HCPs delivering planning consultations (Harrison et al., 2022). An additional perceived benefit not considered in the logic model was the enhancement of patients' sense of control and empowerment over their treatment. The TPCI app was also perceived to be helpful to clinics in easing patient management, promoting patient-centred care and decreasing staff burden/time in patient communication requirements. Overall results indicate the TPCI adequately targets outcomes that are highly valued by ART stakeholders.

If the TPCI is to be successfully implemented in clinics, barriers to its implementation will need to be addressed. The most relevant ones pertain to HCP ambivalence towards a practice shift to multi-cycle planning and concerns about the practicalities of implementing the TPCI, for instance time to administer the TPCI Checklist.

Anticipating unintended negative effects of the TPCI is an important conceptual issue that needs to be considered prior to and during implementation research. The implementation of the TPCI could have negative effects for groups of patients who are unable to plan for (and access) multiple cycles of treatment (e.g. affordability). While we acknowledge that certain individuals will benefit from multi-cycle planning more than others (e.g. good treatment prognosis, financially able), based on our previous research findings (Harrison et al., 2021, 2022) and ethical requirements regarding information provision (Gameiro et al., 2013), we would argue the TPCI to be relevant to all patients to support patient expectations. However, we suggest based on our previous research (Harrison et al., 2022), the current results and the review process, that the app should be modified to tailor information and signposting to sources of support according to patient input based on their individual profile and/or circumstances (i.e. the number of cycles the patient plans to undergo). We also acknowledge that treatment is accompanied by clinical judgement applied by HCPs responsible for patient care particularly if/when continuation of treatment does not prove to be a viable option. Therefore, although the TPCI encourages patients to plan for multiple cycles of treatment, it recognizes that initial treatment plans may need to be revised throughout the treatment journey. For example, if an individual initially plans to have three cycles of treatment but after the first cycle the HCP recommends no more treatment, the patient can change their treatment plan within the app and the app will respond sensitively, by following best practice in sharing bad news in fertility care (Leone et al., 2017), and accordingly, for instance by directing patients to sources of support outside the TPCI (e.g. information and support for unsuccessful treatment https://myjourney.pt/patient). In sum, we suggest the app incorporates consequence management (i.e. consideration of the wider ramifications of the implementation and use of the TPCI for patients), by signposting patients to relevant information and support to help prevent or minimize any unintended negative effects (e.g. distress or regret).

Another potential negative effect of the TPCI is that its use could (or could seem to) promote overexploitation or catastrophic health expenditure (Dyer et al., 2013). Previous research suggests that as patients progress through treatment, they become more focused on the child wish and are more impaired in their ability to decide to stop treatment (Carson et al., 2021). In this respect, we would argue that the TPCI also aims to prevent decision-making at times of treatment when patient's decision-making ability may be impaired (Rauprich et al., 2011) and could lead to overtreatment. The TPCI therefore aims to ensure that patients are well counselled about the possibility of treatment failure (Rauprich et al., 2011) from the outset of treatment. The TPCI aims to support expectation management prior to treatment by discussing cumulative success rates with patients. As suggested by our previous research (Harrison et al., 2022), these success rates should be informed by NICE guidelines (three cycles) and should also acknowledge variability in success rates within and between age groups based on individual profiles and circumstances, so that individuals have a realistic outlook of their chances of success at the start of treatment (Harrison et al., 2022). Cumulative success rates therefore highlight that some patients may need to undergo more treatment than others, and that success is still not guaranteed even after multiple cycles of treatment. This approach has previously been suggested to support decision-making about whether and when to stop treatment and reduce the possibility of overtreatment (Carson et al., 2021; Rauprich et al., 2011). By signposting to appropriate support at the end of patients' (unsuccessful) treatment plan the TPCI empowers patients to access tools proven to ease this transition (Rowbottom et al., 2022). Together, these strategies are suggested to reduce the time it takes to achieve a pregnancy/live birth or achieve peace of mind or a sense that they have tried their best (given available resources) to achieve a pregnancy when deciding to discontinue treatment.

Implementation and evaluation of the TPCI should help better identify the necessary signposting to be incorporated into the app, in addition to monitoring the potential unintended negative effects of the TPCI. More research is needed to better understand what patients consider to be necessary to achieve 'peace of mind' when deciding to discontinue treatment, and what constitutes a 'good' initial plan from the patients' and healthcare professionals' perspectives. For example, is planning for three complete cycles universally recognized as a good

plan? Can HCPs support patients in deciding what is a good initial plan? Using TPCI type apps will help identify what works best by way of planning and supporting the implementation and cessation of plans, because it offers a structured and standardized approach. Results also indicate that further feasibility testing needs to account for implementation barriers (see Bonell *et al.*, 2015).

The practicalities of implementing the TPCI also need consideration. While other formats of delivering the TPCI may be possible, other methods may be more time-consuming and could have additional trade-offs such as fewer people receiving the same care. For example, some suggestions provided by HCPs were for counsellors to have an active role in the delivery of the TPCI checklist or for new consultants to be trained to deliver the multi-cycle consultations. However, if such methods were adopted, not all individuals would be exposed to multi-cycle consultations because not all consultants might be trained and not all patients receive counselling support prior to treatment engagement. These issues, coupled with previous research indicating preferences for digital technologies for patients (e.g. Robertson *et al.*, 2022), suggest the TPCI in its current format (i.e. checklist and app) to be the most accessible way to promote multi-cycle planning and provides patients with information and support throughout the treatment journey. Distribution and adherence to the TPCI checklist across clinics would encourage a shift to multi-cycle planning. This expectation is based on other practice shifts (e.g. double to single embryo transfer), which suggest that adherence to multi-cycle planning would be expected to increase progressively as the evidence base in support increases and attracts endorsement from guidelines, regulators, and other relevant stakeholders. A practice shift is more likely if any perceived potential barriers are avoided. Implementation of the TPCI and associated evaluative research would therefore help to identify any potential barriers to making multi-cycle planning standard practice in reproductive care.

Acceptability of TPCI coupled with repeated reports of intentions and willingness to use it in the future among HCPs and patients suggests the TPCI could successfully and significantly expand the current portfolio of IVF/fertility treatment digital applications, by addressing an unmet need in patient support that promotes valued outcomes. As noted, existing digital support tools mainly focus on the provision of practical and coping information and, while these were considered valuable (Meyers and Domar, 2021; Robertson*et al.*, 2021), integrating the psychological and emotional support needs of patients in relation to treatment planning and continuation were considered unique by HCPs and patients. The perceived value of the TPCI can further be enhanced by extending its use to be applicable to partners and other patient populations and/or adding other support features (e.g. virtual connection to other patients), as suggested. Digital support is increasingly an important asset given research indicating digital interaction may be preferred options for younger patients (both fertile and infertile) and may be well suited to manage coronavirus (COVID) related restrictions (Boivin *et al.*, 2020; Vogler and Lightner, 2020). Increasingly, patients use and probably expect to use digital support in clinics for varied needs (Robertson *et al.*, 2021, 2022). In due course, digital support apps targeting other support needs could be integrated but acceptability, feasibility and efficacy of individual components will always be precursors to such integration.

The results of this study point to the need to ascertain the feasibility of implementing the TPCI. A feasibility study would need to address current main uncertainties: (i) will the TPCI be enough to create a practice shift from cycle-by-cycle to multi-cycle planning; (ii) can it be successfully implemented and integrated within existing clinical processes (e.g. can physicians use the checklist within time of planning consultation) and culture (e.g. can mistrust related to financial exploitation be overcome); (iii) will high willingness to use translate in actual sustained engagement with the TPCI within and across ART cycles; (iv) can any unintended negative effects be prevented (e.g. negative impact of monitoring, negative impact on those only wanting or able to do one cycle, patient exploitation); and (v) can magnitude of expected benefits be estimated. If feasibility is established, the need to examine implementation from the perspective of multiple providers suggests a pragmatic cluster randomized trial will be the most appropriate way to move forward.

Strengths and limitations

All patients were women, recruited from social media websites, typically associated with patient support groups. HCPs were by majority consultants from private clinics that could have different perspectives on digital support from doctors operating in publicly funded centres. Consequently, the views expressed may reflect the profile of people from these settings rather than patients and HCPs in general. Other limitations include the fact that seven patients and six HCPs could not directly interact with the TCPI due to restrictions in the device they were using. The lack of physical agency for these participants could have affected perceptions. Finally, the interviewer is part of the TPCI research and development team, and this could have affected the way participants expressed their views, even though they were reassured that all feedback, both positive and negative was welcome. Overall, these limitations may translate in over-positive acceptability reports. However, the convergence of results with other research on the planning of treatment, patient support and use of digital support suggests that such participant bias is unlikely to invalidate conclusion that further testing of the TPCI is warranted. The fact that many participants also expressed concerns, ambivalence and suggestions for enhancements offers reassurance that a full range of reactions to and views of the TPCI were captured.

Conclusion

Results demonstrate the acceptability of the TPCI as a novel intervention that can prepare and support patients during fertility treatment in a way that is perceived to reduce the risk of treatment discontinuation. Positive valuing of the intervention and its concepts also demonstrates acceptability of introducing a paradigm change from single to multi-cycle planning to strengthen personal treatment plans and treatment recommendations. Future research should prioritize feasibility testing with integrated process evaluation to examine the use of the TPCI by clinics and patients, barriers, and facilitators to implementation in clinics in the UK, detection of possible unintended outcomes and estimation of effect on hypothesized outcomes.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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Authors' roles

C.H., S.G. and J.B. contributed to the conception and design of the study, the acquisition of data and the analysis and interpretation of the data. All authors drafted all versions of the article and approved the final version for publication.

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Conflict of interest

J.B. reports personal fees from Merck KGaA, Darmstadt, Germany, Merck AB an affiliate of Merck KGaA, Darmstadt Germany, Theramex, Organon JJC, Ferring Pharmaceuticals A/S, research grant from Merck Serono Ltd, grants from ESHRE outside the submitted work and that she is co-developer of Fertility Quality of Life (FertiQoL) and MediEmo app. S.G. reports consultancy fees from TMRW Life Sciences and Ferring Pharmaceuticals A/S, speaker fees from Access Fertility, SONA-Pharm LLC, Meridiano Congress International and Gedeon Richter. C.H. declares no conflicts of interest.

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