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ORIGINAL ARTICLE ***Psychology and counselling***

Systematic development of a mobile preconception lifestyle programme for couples undergoing IVF: the PreLiFe-programme

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STUDY QUESTION: Can we develop a preconception lifestyle programme for couples undergoing IVF that is in line with their needs.

SUMMARY ANSWER: A mobile preconception lifestyle programme was systematically developed based on expert opinion, literature and needs of IVF-patients.

WHAT IS KNOWN ALREADY: A healthy lifestyle prior to conception is not only beneficial for the general health of couples, but evidence on its importance for their reproductive health and the health of their children is also emerging. So far, the vast majority of fertility clinics do not offer a lifestyle programme for couples undergoing IVF. Therefore, the present study aimed to develop a lifestyle programme for IVF-couples.

STUDY DESIGN, SIZE, DURATION: The development of the PreLiFe-programme was guided by the steps of the Medical Research Council (MRC) framework for developing complex interventions, a systematic approach for developing theory- and evidence-based health promotion interventions.

PARTICIPANTS/MATERIALS, SETTINGS, METHODS: First, the evidence base on lifestyle programmes for IVF-couples was reviewed. Second, several iterations between an expert panel, the literature, and quantitative and qualitative data from IVF-patients identified the content, the format, behaviour change techniques and theory of the programme. Third, the PreLiFe-programme was produced and the expected process and outcomes of a randomized controlled trial assessing it were modelled. Finally, user tests among experts and patients and pilot tests among patients were conducted.

MAIN RESULTS AND ROLE OF CHANCE: The finally developed PreLiFe-programme is a mobile application to be used autonomously by both partners of IVF-couples during the first year of IVF, in combination with motivational interviewing over the telephone every three months (i.e. blended care). The PreLiFe-programme provides advice and skills training on physical activity, diet and mindfulness based stress reduction and is in part tailored based on monitoring and tracking the lifestyle of patients. Based on the literature the expert panel considers it plausible that all three components contribute to IVF-success rates. The PreLiFe-programme is likely to be acceptable to patients as it meets the need of patients for lifestyle advice and treatment information.

LIMITATIONS, REASON FOR CAUTION: The pilot in IVF-couples had a 3-month duration. The feasibility of the PreLiFe-programme in other infertile populations and/or upon longer use is yet to be examined. Whether the PreLiFe-programme effectively improves lifestyle and IVF-success rates is currently being examined in a trial randomizing heterosexual couples starting IVF to the PreLiFe-programme or an attention-control group for 12 months.

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WIDER IMPLICATIONS OF THE FINDINGS: If the PreLiFe-programme improves lifestyle and the chance of IVF-success, it will be a powerful tool and provide guidance for implementing lifestyle programmes in fertility clinics.

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Introduction

The life plan for the vast majority of people includes having children. However, 1 in 10 couples are faced with infertility, defined as failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (Zegers-Hochschild *et al.*, 2017). About half of these couples decide to turn to fertility treatment, including IVF with or without ICSI (Boivin *et al.*, 2007). In Belgium, the live birth rate after three completed IVF/ICSI cycles or one year of IVF is approximately 50% (Peeraer *et al.*, 2014; De Neubourg *et al.*, 2016). However, infertility and its treatment result in a considerable emotional and economic burden for both individuals and society (Gameiro *et al.*, 2012; Wu *et al.*, 2013). Addressing modifiable factors, which can reduce this burden and improve the chance of IVF-success, are, therefore, important research priorities for the field of reproductive medicine (Gameiro *et al.*, 2013a; Moran *et al.*, 2016). Lifestyle is such a modifiable factor, and following a healthy lifestyle is not only beneficial for the general health of infertile men and women but also for their reproductive health and for the health of their children (Homan *et al.*, 2007; Stephenson *et al.*, 2018). A guideline of the European Society of Human Reproduction and Embryology (ESHRE) highlighted the need for interdisciplinary developed programmes that meet the emotional, relational and cognitive needs of fertility patients, as well as their need for advice on lifestyle behaviour modification (Gameiro *et al.*, 2015). So far, the vast majority of fertility clinics do not yet offer a lifestyle programme to couples undergoing IVF. This might explain why one in three IVF-couples seeks complementary therapy outside of their fertility clinic including lifestyle and/or psychosocial support (Smith *et al.*, 2010; Porat-Katz *et al.*, 2016). Mobile applications have a promising format for lifestyle interventions, proven effective in other patient populations for being time-efficient and empowering patients (Afshin *et al.*, 2016).

This paper describes the systematic development of a preconception lifestyle programme for IVF-couples, the PreLiFe-programme. We aimed to develop an innovative mobile application for IVF-couples based on expert opinion, the needs of IVF-couples, the literature on the relationship between lifestyle and IVF-success, and on behaviour change techniques.

Materials and methods

The PreLiFe-programme was developed at Leuven University (Belgium; October 2017–January 2019), by following the first two stages of the framework of the Medical Research Council (MRC) for developing and evaluating evidence and theory-based complex interventions (Craig *et al.*, 2013). These stages devoted to 'development', and 'feasibility and piloting' and are each split up in three steps (Fig. 1).

Stage 1: Development

Step 1: Identifying the evidence base

The evidence base on the effect of (complex) interventions focussing on diet and/or physical activity on lifestyle and IVF-success was reviewed until January 2019 (Craig *et al.*, 2013). In line with the hierarchy of evidence, systematic reviews and (non-) randomized controlled trials (RCTs) were considered superior to evidence from cohort studies (Evans, 2003).

Step 2: Identifying components and developing a plausible theory

Experts, IVF-patients and the literature were consulted during the development of the PreLiFe-programme and a plausible theory of how it can increase IVF-success was developed (Craig *et al.*, 2013). Involving patients in the development of a novel intervention is in line with the principles of patient-centred care (Corrigan *et al.*, 2001; Crawford *et al.*, 2002; Nilsen *et al.*, 2006).

The repeatedly consulted (i.e. iterative process) interdisciplinary PreLiFe-expert panel included 15 persons: physical activity promotion researchers (n = 2), nutrition promotion researchers (n = 2), psychologists specialized in mindfulness (n = 3), sociologists specialized in user experience research (n = 2), software developers (n = 2), gynaecologists (n = 2), an embryologist (n = 1) and a midwife specialized in the field of reproductive medicine (n = 1).

The IVF-patients were consulted in two small scale studies. First, a qualitative study explored the needs regarding a lifestyle programme of a convenience sample of Dutch speaking heterosexual male and female IVF-patients, volunteering based on a post on the website of the Belgian association for fertility patients and via a flyer in the waiting room of two University fertility clinics. More specifically, the female interviewer (RV, sociologist not involved in fertility care) relied on three open-ended questions (Supplementary Table SI) and a topic list for conducting the in-depth interviews of about one hour at the participant's home. The interviews were audio recorded, transcribed and subjected to inductive content analysis by a single researcher (RV). The analysis was not performed with a specialized software and member checking was not performed. Data-collection and analysis were intertwined processes and the sample size was defined by data saturation. Exemplifying interview quotations illustrate the findings. Second, a cross-sectional survey explored the diet and physical activity of Dutch speaking heterosexual couples about to start IVF at a Belgian University fertility clinic with the Food Frequency Questionnaire (FFQ; Matthys *et al.*, 2015) and the International Physical Activity

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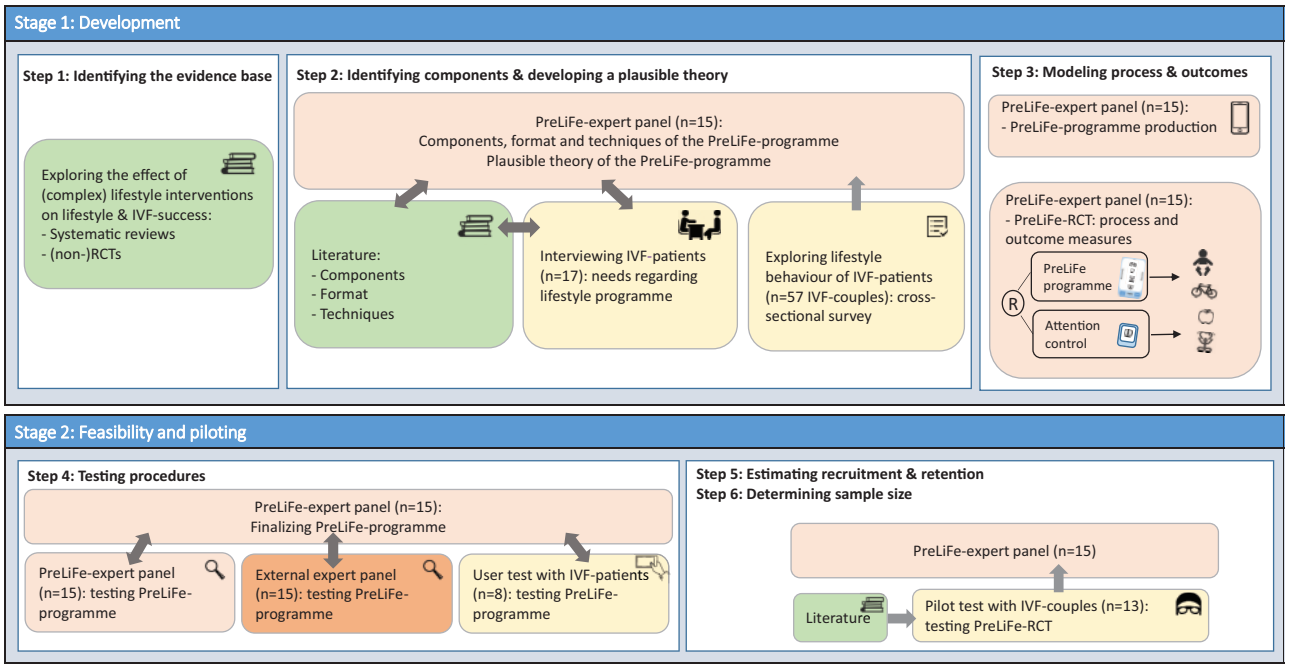

Figure 1. Stages and steps of the development of the PreLiFe-programme. RCT, randomized controlled trial.

Questionnaire (IPAQ; Craig *et al.*, 2003). This cross-sectional survey did not assess the distress of IVF-couples, as the decision to address distress with the lifestyle programme was taken afterwards. Moreover, the distress of IVF-couples has been demonstrated by ample previous studies (Gameiro *et al.*, 2015). The 31-items FFQ questions the frequency and portion size of consumed food and beverages, and allows assessing whether the dietary pattern is in line with WHO and national recommendations (Gezondheidsraad, 2016; GEZOND LEVEN, 2018; WHO, 2018a). The 7-items IPAQ questions the frequency and duration of physical activities and allows assessing whether the amount spent on moderate to vigorous physical activity is in line with recommendations (GEZOND LEVEN, 2018; WHO, 2018b). Table I presents the sociodemographic and clinical characteristics of the 84 female and the 73 male IVF-patients consulted during the development and pilot of the PreLiFe-programme.

The literature on the relation between lifestyle and IVF-success was reviewed until January 2019. This review was more elaborate than the review presented in step 1 as it: (i) focussed on all components proposed by the PreLiFe-expert panel and patients, rather than only physical activity and/or diet and (ii) included cohort studies examining associations besides non-RCTs (nRCTs). In addition, the literature on the format of lifestyle interventions and on behaviour change techniques was consulted.

Step 3: Modelling process and outcomes

The project coordinator (TB) and the PreLiFe-expert panel modelled the complex intervention in detail (i.e. programme production; Craig *et al.*, 2013). A team of software engineers and web designers built the mobile application.

The PreLiFe-expert panel selected reliable and valid process and outcome measures for assessing the plausible theory in an RCT.

Stage 2: Feasibility and piloting

Step 4: Testing procedures

The PreLiFe-expert panel and an external expert panel used the PreLiFe-programme for one week and assessed whether the intended behaviour change techniques were present and identified opportunities for improvement. The external expert panel from Ghent University (n = 15) were all health promotion researchers (psychologists, physicians and others with a master of science in health promotion) with a research focus on: physical activity (n = 8), nutrition (n = 2), mental health (n = 5). In addition, eight IVF-patients (also taking part in the interview study; Table I) were observed and questioned on feasibility, user-friendliness and opportunities for improvement whilst using the PreLiFe-programme. The female researcher (RV, sociologist not involved in fertility care) relied on the think aloud technique and semi-structured interview questions/tasks, audio recorded the interviews and analysed them in a reflective report per interview (Broekhuis *et al.*, 2019).

Step 5: Estimating recruitment and retention

The PreLiFe-expert panel reviewed the literature on recruitment and retention in RCTs assessing complex lifestyle interventions in the field of reproductive medicine. The PreLiFe-programme and the PreLiFe-RCT were pilot tested for three months among 13 Dutch speaking heterosexual couples about to start IVF in a Belgian University fertility clinic (Table I).

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Table I Sociodemographic and clinical characteristics of the 84 women and 73 men studied during the development of the PreLiFe-programme.

	Qualitative study		Cross-sectional survey		User test*		Pilot test	
	Women (n = 14)	Men (n = 3)	Women (n = 57)	Men (n = 57)	Women (n = 7)	Men (n = 1)	Women (n = 13)	Men (n = 13)
Sociodemographic characteristics								
Proportion of whom partner participated in study (%)	2 (14%)	2 (67%)	57 (100%)		1 (14%)	1 (100%)	26 (100%)	
Mean age (SD)	35.38 (±5.27)	34.0 (±6.08)	32.98 (±4.75)	36.37 (±6.76)	37.17 (±4.90)	41 (±0.00)	29.92 (±4.44)	32.85 (±4.81)
Proportion with (University) College degree (%)	11 (79%)	2 (67%)	NA	NA	5 (71%)	1 (100%)	12 (92%)	9 (69%)
Clinical characteristics								
Mean Body mass index in kg/m^2 (SD)	NA	NA	23.61 (±4.26)	26.61 (±4.79)	NA	NA	26.64 (±4.38)	23.43 (±4.19)
Mean duration of infertility in years (SD)	2.06 (±1.24)	2 (±0.00)	1.91 (±1.09)		2.03 (±1.33)	2 (±0.00)	2.61 (±1.19)	
Treatment stage								
• **About to start IVF**	2 (14%)	0 (0%)	57 (100%)		1 (14%)	0 (0%)	26 (100%)	
• **2nd–4th IVF-cycle**	6 (43%)	2 (67%)	0 (0%)		3 (43%)	1 (100%)	0 (0%)	
• **Conceived with IVF**	6 (43%)	1 (33%)	0 (0%)		3 (43%)	0 (0%)	0 (0%)	

*All individuals taking part in the user tests, already took part in the qualitative study.
NA: not assessed.

Step 6: Determining sample size

The PreLiFe-expert panel based the sample size of the PreLiFe-RCT on the reproductive medicine literature.

Results

Step 1: The evidence base

In line with two systematic reviews of RCTs examining the effect of lifestyle interventions on infertile couples' lifestyle and/or IVF-success rate, our review concluded that RCTs were scarce (Anderson *et al.*, 2010; Lan *et al.*, 2017). No RCT examined the effect of a lifestyle intervention in the general population of women and/or men going through IVF (Table II). The available RCTs (n = 8) focussed exclusively on infertile women who suffered from overweight or obesity, in whom lifestyle interventions improved natural pregnancy rate (odds ratio (OR): 1.87, 95% CI: 1.24–2.81) (Lan *et al.*, 2017). The literature review prior to finalizing the PreLiFe-programme in January 2019 identified three nRCTs among IVF-couples, showing that a lifestyle intervention focussing on diet, or on diet and physical activity, improved diet (n = 1) or diet and physical activity level (n = 2; Table II). One nRCT improved the chance of becoming pregnant via natural or IVF-conception (no subgroup analysis; van Dijk *et al.*, 2017) and the others did not examine IVF-success (Homan *et al.*, 2012; Hammiche *et al.*, 2011).

Step 2: The identified components and developed plausible theory

After several iterations, the expert panel decided on the components, format and techniques of the PreLiFe-programme and finalized a plausible theory of how the novel PreLiFe-programme can improve lifestyle and IVF-success.

Components of the PreLiFe-programme

After several iterations between the literature, the interviews with IVF-patients and after the cross-sectional survey in IVF-patients, the PreLiFe-expert panel decided to focus on the following three lifestyle factors: physical activity, diet and mindfulness. The interviews showed that patients want to improve their lifestyle in order to regain control during IVF, as exemplified in the following interview quotation: *'They give very little information, why it fails, what you can do yourself, diet tips, exercise tips? What can you do yourself? That is very important to me'* (Interview 17, woman). Table II outlines the underlying literature and identified needs of IVF-patients, explaining why the expert panel considers it plausible that each component improves lifestyle behaviour and IVF-success. Figure 2 displays the theory based on which the PreLiFe-expert panel considers it plausible that the PreLiFe-programme will improve IVF-success.

In order to increase its acceptability to patients, the PreLiFe-programme additionally includes reminders for medication, consults and procedural treatment information. This feature has been prioritized by infertile patients (Dancet *et al.*, 2011) and is in line with the needs of interviewed patients, as exemplified by following quotation: *'Step by step information would be very nice'* (Interview 2, man).

Physical activity In line with the World Health Organization (WHO) and national recommendations, the PreLiFe-programme stimulates IVF-couples to do at least 150 min of moderate physical activity per week and at least 10 000 steps per day (GEZOND LEVEN, 2018; WHO, 2018b). The cross-sectional survey showed that only two in

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Table II Rationales for the chosen lifestyle components of the complex PreLiFe-programme.

Components	Literature*						IVF-patients: needs identified in qualitative study	Expert panel's final rational for considering it plausible that the PreLiFe-programme improves lifestyle behaviour and IVF-success rates**
	nRCTs in IVF-couples found that (complex) lifestyle interventions resulted in:				(Guidelines summarizing) RCTs in healthy individuals or patients with various conditions found that (complex) lifestyle interventions resulted in improved lifestyle & general health	Observational studies in IVF-couples found associations between advised lifestyle behaviour and IVF-success rates		
	Improved lifestyle		Improved IVF-success rates					
	RCT	nRCT	RCT	nRCT				
Physical activity (PA) Stimulating moderate PA		Improved PA ♂♀ (A, B)		NA	Improved moderate PA level and general health in healthy ♂ and ♀, ♀ in their perinatal period and ♂ and ♀ with various conditions*** (C-F)	Positive association between moderate PA in ♀ and IVF-success and between moderate PA in ♂ and semen quality (G, H)	Need for advice on PA: *'Yes, I have many questions such as: can I stay active during my fertility treatment?'* (Interview 10, woman)	Based on the literature an increase in PA and IVF-success rate is plausible, especially as the PreLiFe-programme addresses both partners (J).
Reducing sedentary behaviour stimulating daily physical activity					Decreased sedentary behaviour and improved general health in healthy ♂ and ♀, ♀ in their perinatal period and ♂ and ♀ with various conditions*** (C-F, I)			
Diet Stimulating healthy dietary pattern & food literacy		Improved diet ♂♀ (A, B, K)		NA	Improved diet and general health in healthy ♂ and ♀ and ♂ and ♀ with various conditions**** (L, M)	Positive association between a healthy dietary pattern in ♂ and ♀ and IVF-success (N-Q)	Need for dietary advice: *'It might be nice to be provided with menus. Menus consisting of foods that have a positive effect on your fertility.'* (Interview 10, woman)	Based on the literature an improvement of diet and IVF-success rate is plausible, especially as the PreLiFe-programme addresses both partners (J, K). The PreLiFe-expert panel expects that the focus on food literacy in addition to dietary pattern will increase the likelihood of an improved diet (R, S). Of note, the only one in three non-RCTs that reported effects on success rates reported an improved pregnancy rate but included naturally besides IVF-conceived pregnancies and did not report sub-group analyses (K).

(continued)

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Table II Continued

Components	Literature*						IVF-patients: needs identified in qualitative study	Expert panel's final rational for considering it plausible that the PreLiFe-programme improves lifestyle behaviour and IVF-success rates**
	nRCTs in IVF-couples found that (complex) lifestyle interventions resulted in:				(Guidelines summarizing) RCTs in healthy individuals or patients with various conditions found that (complex) lifestyle interventions resulted in improved lifestyle & general health	Observational studies in IVF-couples found associations between advised lifestyle behaviour and IVF-success rates		
	Improved lifestyle		Improved IVF-success rates					
	RCT	nRCT	RCT	nRCT				
Mindfulness-based stress reduction (MBSR)	Reduced emotional distress ♀ (T, U)		Improved IVF-success rate (T)		Reduced emotional distress in healthy ♂ and ♀ and ♂ and ♀ with various conditions***** (V, W)	Evidence inconclusive on association between emotional distress in ♂ and ♀and IVF-success rate (X, Y)	Need for accessible strategy to reduce emotional distress: '*There should be attention for relaxation and stress release. The mental part is also important. For example, focus on your breath, drink a nice tea. . . Small, accessible things that support to patients.*' (Interview 17, woman)	Based on the literature a decrease in emotional distress and an increase in IVF-success rate is plausible. On the one hand, evidence on the association between distress and IVF-success rate is inconclusive (X, Y). On the other hand, the improved pregnancy rates in the RCT on MBSR (T) might be due to a decrease in IVF-discontinuation, which might in turn increases IVF-success rates. Distress has been reported as a reason for IVF-discontinuation (Z) and IVF-compliance has been related to IVF-success (AA).

RCT, randomized controlled trial;
nRCT, non-randomized controlled trial;
PA, physical activity;
MBSR, mindfulness-based stress reduction;
NA, not assessed.
*Evidence published prior to the finalization of the programme (January 2019).
**Final opinion after several iterations between the literature, patients and experts.
***Examples of conditions in which improved physical activity and general health was demonstrated: noncommunicable diseases (NCDs).
****Examples of conditions in which improved diet and general health was demonstrated: NCDs.
*****Examples of conditions in which reduced emotional distress was demonstrated: NCDs, psychological problems.

A. Homan *et al.* (2012). B. Hammiche *et al.* (2011). C. WHO fact sheet on physical activity (2018b). D. Harrison *et al.* (2016). E. Penedo *et al.* (2005). F. Warburton and Bredin (2017). G. Ibanez-Perez *et al.* (2019). H. Rao *et al.* (2018). I. GezondLeven (2018). J. Best *et al.* (2017). K. van Dijk *et al.* (2017). L. WHO fact sheet on nutrition (2018a). M. Hoge Gezondheidsraad (2016). N. Salas-Huetos *et al.* (2017). O. Twigt *et al.* (2012). P. van Dijk *et al.* (2016). Q. Vujkovic *et al.* (2010). R. Vidgen and Gallegos (2014). S. Azevedo Perry *et al.* (2017). T. Li *et al.* (2016). U. Nery *et al.* (2019). V. Gotink *et al.* (2015). W. Khoury *et al.* (2013). X. Boivin *et al.* (2011). Y. Matthiesen *et al.* (2011). Z. Gameiro *et al.* (2012). AA. Gameiro *et al.* (2013a, 2013b).

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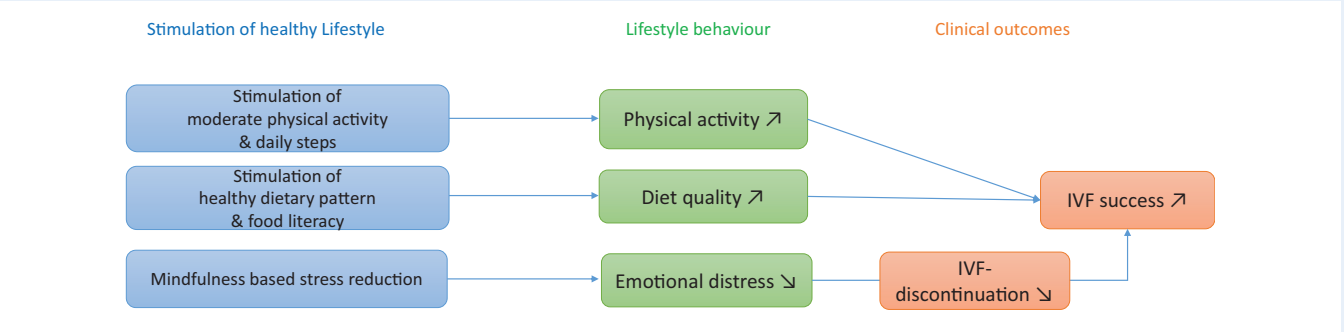

Figure 2. The plausible theory of the PreLiFe-programme.

three (fe)male IVF-patients perform the recommended 150 minutes of moderate physical activity per week (Supplementary Table SII). Based on the literature, the PreLiFe-expert panel considers it plausible that stimulating moderate physical activity and the number of daily steps improves the physical activity level (i.e. nRCTs in IVF-couples and RCTs in other patients populations) and IVF-success (i.e. observed association between physical activity level and IVF-success) of IVF-couples (Table II) (Penedo and Dahn, 2005; Hammiche *et al.*, 2011; Homan *et al.*, 2012; Harrison *et al.*, 2016; Warburton and Bredin, 2017; Rao *et al.*, 2018; Ibanez-Perez *et al.*, 2019). The PreLiFe-expert panel expects that advice on physical activity will be acceptable to patients as the interviewed IVF-patients shared their need for advice on physical activity (Table II).

Diet In line with WHO and national recommendations, the PreLiFe-programme stimulates IVF-couples to have a healthy dietary pattern (Gezondheidsraad, 2016; GEZOND LEVEN, 2018; WHO, 2018a). Based on expert opinion, the PreLiFe-programme will focus on food literacy in addition to a healthy dietary pattern (Table II). Food literacy is an evidence-based model focussing on all practicalities of healthy eating, such as food planning, selecting foods, food preparation and evaluating information about food (Vidgen and Gallegos, 2014; Azevedo Perry *et al.*, 2017; Truman *et al.*, 2017). Healthy dietary pattern and food literacy has been operationalized into 24 goals (Boedt *et al.*, 2019b). The cross-sectional survey showed that depending on the type of food, only 5–42% of (fe)male IVF-patients meet the recommended daily intake (Supplementary Table SII). Based on the literature, the PreLiFe-expert panel considers it plausible that stimulating a healthy dietary pattern and food literacy improves the diet (nRCTs in IVF-couples and RCTs in other patients populations) and IVF-success (observed association between diet and IVF-success) of IVF-couples (Table II) (Vujkovic *et al.*, 2010; Hammiche *et al.*, 2011; Homan *et al.*, 2012; Twigt *et al.*, 2012; van Dijk *et al.*, 2016; Gezondheidsraad, 2016; van Dijk *et al.*, 2017; Salas-Huetos *et al.*, 2017). The PreLiFe-expert panel expects dietary advice of IVF-couples to be acceptable to patients as the interviewed IVF-patients shared their need for dietary advice, including recipes (Table II).

Mindfulness The PreLiFe-programme includes mindfulness-based stress reduction exercises, that stimulate patients to become non-judgmentally aware of thoughts, feelings, and sensations, and increase their capacity to replace automatic, habitual, and often judgmental reactions with more conscious and skilful responses (Maex, 2010; Kabat-Zinn, 2013; Crane *et al.*, 2017). The fact that couples are distressed during IVF is well documented (Cousineau and Domar, 2007; Gameiro *et al.*, 2015). Based on the literature, the PreLiFe-expert panel considers it plausible that mindfulness-based stress reduction lowers distress in IVF-couples (RCTs in IVF-women and RCTs in male and female patients with other conditions) and that it improves IVF-success (RCT in IVF-women) (Table II) (Khoury *et al.*, 2013; Gotink *et al.*, 2015; Li *et al.*, 2016; Nery *et al.*, 2019). Of note, the evidence on the association between distress and IVF-success is inconclusive (Boivin *et al.*, 2011; Matthiesen *et al.*, 2011). The PreLiFe-expert panel considers it plausible that mindfulness-based stress reduction improves IVF-success by limiting IVF-discontinuation (Table II) (Gameiro *et al.*, 2012, 2013b). The PreLiFe-expert panel expects that offering mindfulness-based stress reduction is acceptable to patients, as the IVF-patients interviewed shared their need for an accessible strategy to limit distress (Table II).

Format of the PreLiFe-programme

The predefined format of a mobile application was in line with patients' needs for a time efficient intervention, as exemplified by the following interview quotation: *'IVF itself is already time consuming, so please an intervention that does not require visits to the clinic'* (Interview 10, woman). The PreLiFe-expert panel opted for 'blended care' by building the ability to chat with health care professionals into the mobile application. This decision was based on an RCT showing that adding interaction with healthcare professionals to a mobile application improved its effect on lifestyle behaviour (Hurkmans *et al.*, 2018), and to facilitate implementation (Aarts *et al.*, 2015). Offering the possibility to interact with health care professionals is in line with patients' needs, as exemplified in the following interview quotation: *'We decided to no longer search information on the internet. This drives you crazy after a while. I no longer read information, the physician will tell me what to do'* (Interview 1, woman). In addition, the PreLiFe-expert panel decided to address both partners of IVF-couples, as our cross-sectional survey showed that the dietary pattern of partners is correlated ($r = .537$, $P = 0.001$) (Boedt *et al.*, 2019). Furthermore, addressing couples, rather than individuals, proved to maximise compliance rates and the effect of lifestyle interventions on behaviour (Black *et al.*, 1990; Best *et al.*, 2017; van Dijk *et al.*, 2017). This approach is also in line with patient's needs as exemplified by the following quote: *'I always join my partner on visits to the clinic. I really try to be involved'* (Interview 4, men).

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Techniques of the PreLiFe-programme

Table III presents the techniques of the PreLiFe-programme and their match with the self-determination theory for human motivation, specifying that the human need for autonomy, competence and relatedness (Table III) should be met in order to attain positive behavioural outcomes (Ryan and Deci, 2000).

The techniques of the PreLiFe-programme operationalized the following four behaviour change techniques: goal-setting (e.g. 10 000 steps/day), motivational interviewing (i.e. by telephone), tailoring (techniques in '*italic*' Table III) and providing information via imagery (e.g. infographic on preparing a healthy week menu) (Eldredge *et al.*, 2016; Kok *et al.*, 2016). Interestingly, motivational interviewing is especially relevant for applying the self-determination theory in practice (Markland *et al.*, 2005) and has proven to be able to change the lifestyle behaviour of IVF-couples (Homan *et al.*, 2012).

Step 3: Modelling process and outcomes

PreLiFe-programme

The PreLiFe-programme is a mobile application, developed to be used during the first year of the IVF-treatment trajectory. The PreLiFe-programme was developed to be used autonomously by women and men going through IVF. Both individuals of participating couples receive their own login to download the PreLiFe-programme on their smartphone. A link between the logins of partners ensures that both partners receive the same treatment information. The PreLiFe-programme offers the possibility to send a chat message to a health care professional (i.e. the PreLiFe-coach), who replies within 72 h. In addition to everything offered by the mobile application, the PreLiFe-coach contacts each patient once every three months (n = 4) by telephone to discuss their lifestyle according to the principles of motivational interviewing (Lussier and Richard, 2007). Figure 3 describes the PreLiFe-programme in detail, including for each of the three lifestyle components the autonomous decisions that can be taken, the monitoring or tracking that is performed and the overview thereof that is provided to patients, and finally the given advice and skills training. Besides lifestyle advice, the PreLiFe-programme includes fertility treatment information (Fig. 3).

The PreLiFe-programme includes a backend server with a secured dashboard interface enabling the PreLiFe-coach to consult the logs and chat function. Regarding physical activity and diet, automated processes tailor the intervention. Monitoring is performed by a physical activity and food literacy questionnaire, and physical activity is tracked by the pedometer of patient's smartphone and the moderate physical activity planner (Fig. 3). Based on this monitoring and tracking the PreLiFe-programme gives patients an overview and proposes physical activity and dietary goals, which should be selected every 2 weeks. After 2 weeks, patients receive a question to evaluate whether the goal was achieved and whether they want to select a new goal. The PreLiFe-programme provides regular tips (every other week for physical activity, every other day for diet) that align with the selected goals (Table III and Fig. 3). Regarding the mindfulness-based stress reduction, the PreLiFe-programme is not tailored automatically. Patients are instructed

Table III Tailored (in italic) and non-tailored techniques of the PreLiFe programme and their match with the self-determination theory for each of the three components.

Self-determination theory		
Autonomy	**Competence**	**Relatedness**
PHYSICAL ACTIVITY + DIET + MINDFULLNESS-BASED STRESS REDUCTION		
Self-selection of component	Library *Possibility to chat with coach* *Motivational interviewing by coach via telephone*	Couple intervention
PHYSICAL ACTIVITY		
Planning moderate physical activity	*Overview of tracked daily steps & planned moderate physical activity* *Goal to increase daily steps and moderate physical activity by 10%/ 2 weeks or until 10.000 steps/day and 150 minutes/week* *Tips aligned with monitoring* *Overview of achieved goals*	
DIET		
Self-selection of 1/3 proposed goals	*Proposition of goals based on monitoring* *Tips aligned with selected goals* *Overview of achieved goals*	
MINDFULNESS BASED STRESS REDUCTION		
No fixed time-frame	Six progressive modules of exercises + additional exercises	

*Physical activity (PA) is monitored at start of intervention with a questionnaire + continuously tracked by moderate PA-planner and pedometer.
**Diet is monitored at start of the intervention with a questionnaire.

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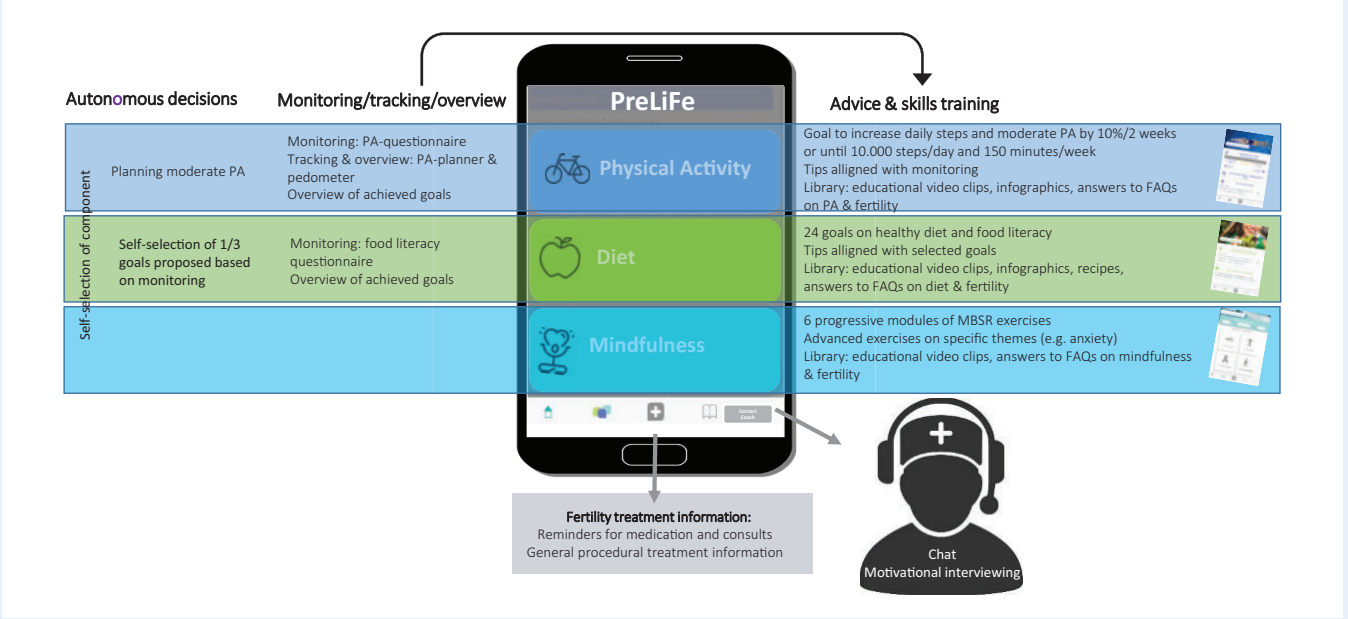

Figure 3. Detailed description of the PreLiFe-programme with a blended care format. FAQs, frequently asked questions; MBSR, mindfulness-based stress reduction; PA, physical activity.

to follow six progressive modules of guided experiential mindfulness based stress reduction exercises (e.g. body scan) in audio-file format. Patients can opt to do a stress test (i.e. an exercise to be kindly aware of stress in your body) (Brewer *et al.*, 2020), and advanced mindfulness exercises on specific themes (e.g. anxiety) are offered.

PreLiFe-RCT

As described in detail in the published protocol of the PreLiFe-RCT, the primary outcome is the cumulative ongoing pregnancy rate achieved within 12 months (Boedt *et al.*, 2019a). As secondary outcomes, the following will be assessed in both partners at baseline 3-, 6-, 9- and 12 months later: physical activity, diet, emotional distress, physical health, fertility related quality of life and partners' support (Boedt *et al.*, 2019a). The PreLiFe-programme logs the use of the programme (i.e. frequency and activity per component) and the acceptability of the PreLiFe-programme is questioned 12-months after randomization.

Step 4: Testing procedures

The PreLiFe-expert panel resolved some slight hitches such as language mistakes and aligned the layout and terminology of the different components. The external expert panel confirmed the presence of the behaviour change techniques. As advised by the external expert panel, the following was added: more recipes to support a healthy diet, and additional practical instructions on the physical activity component. The eight IVF-patients taking part in the user tests (Table I), would recommend the PreLiFe-programme to friends as they found it attractive and easy to use, as exemplified by the following quotation: *'I think it is very useful. When can I start using this app?'* (User test 3, woman). Patients wanted more information on how the PreLiFe-programme works, as exemplified: *'Does the number of goals increase over time or do you start immediately with three goal'* (User test 2, Man). Instruction movies of the gynaecologists from the recruiting clinics, and of the lifestyle experts, were added.

Step 5: Estimating recruitment and retention

Based on the literature and the pilot test, the PreLiFe-expert panel expects a participation rate of 60% and a dropout rate of 20% (Mutsaerts *et al.*, 2016; van Dijk *et al.*, 2016; van Dijk *et al.*, 2017). Of 18 eligible couples addressed for the pilot, 13 couples were randomized (participation rate: 72%; Table I). Three other couples refused as they wanted to focus solely on IVF (n = 2), or as the male partner was not interested (n = 1). An additional two screen failures were due to a spontaneous pregnancy prior to study intake (n = 1) and a male partner not being present at study intake (n = 1). Of the seven couples randomized to the control group, two couples dropped out (15%) due to IVF-discontinuation (n = 1) or wanting to focus solely on IVF (n = 1). None of the couples of the intervention group dropped-out. Of the six couples randomized to the intervention group, five women and five men started to use the PreLiFe-programme within a month. The PreLiFe-programme was used most intensively during controlled ovarian stimulation for IVF.

Step 6: Determining sample size by PreLiFe expert panel

As described in detail in the published protocol of the PreLiFe-RCT, taking account of the literature on cumulative IVF-success rates, IVF-discontinuation rates, study drop-out rates and the plausible effect of lifestyle interventions, led to a sample size of 460 couples (two-sided test; power of 80%; alpha of 5%; study drop-out of 20%) (Boedt *et al.*, 2019a).

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Discussion

This paper reports on the thorough development of the PreLiFe-programme, based on expert opinion, literature and needs of IVF-patients. The finally developed PreLiFe-programme is a novel mobile application to be used autonomously by both partners of IVF-couples during the first year of IVF, in combination with motivational interviewing over the telephone every three months (i.e. blended care). The PreLiFe-programme provides advice and skills training on physical activity, diet and mindfulness based stress reduction and is, in part, tailored based on monitoring and tracking of the patient's lifestyle. Based on the literature, the expert panel considers it plausible that all three components contribute to IVF-success rates. The PreLiFe-programme is likely to be acceptable to patients as it meets their needs for lifestyle advice and treatment information.

The PreLiFe-programme was systematically developed and piloted according to the stages and steps of the framework of the Medical Research Council (Craig *et al.*, 2013). Consulting the literature, experts and patients is expected to result in programmes likely to be effective and likely to be implemented in practice (Craig *et al.*, 2013; Eldredge *et al.*, 2016). To the best of our knowledge, this is the first preconception lifestyle programme in line with the needs of IVF-patients regarding content and format, although the importance of consulting IVF-patients when developing information for them had been highlighted (Dancet *et al.*, 2011; Aarts *et al.*, 2012) and although lifestyle experts had highlighted the need to understand the motivation and context of patients (Barker *et al.*, 2018).

Regarding the consulted literature, prior to finalizing the PreLiFe-programme, trials on the effect of lifestyle interventions in infertile couples were last searched for in January 2019. In the meantime, our group updated the Cochrane systematic review on lifestyle interventions in infertile patients which highlights the need for high-quality studies investigating the effectiveness and safety of preconception advice on a combination of lifestyle factors in men and women with infertility (Boedt *et al.*, 2021). Interestingly, a recent RCT proved that a mobile application focussing on diet, food supplements, smoking and alcohol improved the lifestyle of both partners of IVF-couples (Oostingh *et al.*, 2020). No significant effects on pregnancy rates were found, but the study was not powered to examine this (Oostingh *et al.*, 2020). Of note, the PreLiFe-expert panel only decided to include mindfulness-based stress reduction exercises for addressing the distress of IVF-couples after having consulted IVF-patients at the end of Step 2 of the development of the PreLiFe-programme. Step 1, therefore, only summarizes the evidence base on the effect of interventions focussing on diet and/or physical activity and IVF-couples were only surveyed on their diet and physical activity (Step 2). We did, however, catch-up on reviewing RCTs and cohort studies relevant to mindfulness-based stress reduction exercises when finalizing Step 2. Table II summarizes the rationales for including all three components of the PreLiFe-programme. We did not catch-up on surveying, as several previous surveys demonstrated the distress of IVF-patients (Gameiro *et al.*, 2015).

Regarding the consulted patients, the content analysis of the patient interviews was performed by one researcher only (i.e. no triangulation) and members checking was not performed. The interviewed patients were, however, consulted again when the first version of the programme had been developed. The PreLiFe-programme was developed and is currently tested in heterosexual couples going through IVF (Boedt *et al.*, 2019a). It would be interesting to test and disseminate the PreLiFe-programme in a wider target population than only heterosexual couples going through IVF, including couples who have not yet started IVF as well as single and same sex couples.

The final PreLiFe-programme has interesting features. First, it includes effective behaviour change strategies. Second, The PreLiFe-programme addresses both partners of an IVF-couple affected by the couples' condition (infertility), rather than only the woman, which facilitates extra support and maximises compliance (van Dijk *et al.*, 2016; Best *et al.*, 2017). Third, as advised for lifestyle interventions (Barker *et al.*, 2018), our PreLiFe-programme integrates different lifestyle factors into a complex intervention (physical activity, diet and emotional distress) rather than addressing only one. This includes mindfulness exercises that can contribute to self-care and disease management (Greeson and Chin, 2019). Fourth, its blended care format combining a mobile application with motivational interviewing and chats with the PreLiFe-coach proved to be attractive and engaging for other patient populations (Hurkmans *et al.*, 2018), and is also in line with the needs of interviewed IVF-couples. This format empowers patients to actively manage their health (Afshin *et al.*, 2016) and will enable low-cost widespread implementation of our PreLiFe-programme. The mobile application might, however, give rise to technical problems, such as a mobile phone that has reached its data limit. In addition, patients are likely to want to use the chat function for fertility treatment-related questions while the messaging system is meant for lifestyle-related questions.

This paper outlines the development of the PreLiFe-programme. This detailed description of our lifestyle programme will be informative for other groups developing or selecting preconception lifestyle interventions. Whether the PreLiFe-programme indeed improves the lifestyle or IVF-success rates in IVF-couples is currently being evaluated in an RCT, allocating Belgian heterosexual couples starting IVF to the PreLiFe-programme or an attention-control group for 12 months (Boedt *et al.*, 2019a). If this programme proves to be effective on reproductive and lifestyle outcomes in IVF-couples, it will be a powerful tool and provide guidance for implementing lifestyle programmes as standard care in fertility clinics.

Supplementary data

Supplementary data are available at *Human Reproduction* online.

Data availability

The International Committee of Medical Journal Editors (ICMJE) recommendations will be followed: Individual de-identified participant data underlying this manuscript will be shared upon a reasonable request to the corresponding author (christophe.matthys@uzleuven.be) from investigators having their project approved by an independent review and signing a data access agreement.

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Authors' roles

All authors contributed substantially to the development of the PreLiFe-programme. T.B., S.L.F., D.D.N., S.V., C.S. and D.G. made an essential effort for the acquisition of the patient data. T.B., D.G. and E.A.F.D. analysed and interpreted the data. T.B., C.M. and E.A.F.D. prepared this manuscript and all authors read, revised and approved the final manuscript.

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Conflict of interest

The authors have no conflict of interest to report.

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