Digital tools as parental support – how should they be provided to meet the needs of expecting and new parents?

Submission date 30/09/2020	Recruitment status No longer recruiting	Prospectively registered	
		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
02/10/2020	Completed	[_] Results	
Last Edited 02/02/2022	Condition category Other	Individual participant data	
		[] Record updated in last year	

Plain English summary of protocol

Background and study aims

In recent years, it has become more and more common for expecting parents to turn to digital sources for health information. Overall, there is a rapid development of advanced technology within society, and research shows that humans are finding that the rapid integration of digital technology affects both their personal and professional lives. The access to digital tools for parents is increasing, and further exploration is needed to gain knowledge about parents' experiences from using such tools when preparing for childbirth and parenthood, for example. This study will explore serious games as digital tools for parental support, and both the parents' and healthcare professionals' views will be included. The aims of the study are to explore two different serious games: (1) the 'Childbirth Journey' (Swedish: 'Förlossningsresan') relating to pregnancy, childbirth and parenthood; and (2) 'Interplay' (Swedish: 'Samspel') relating to the parental relationship and parenthood.

Who can participate?

Expecting and new parents in a county within the south-west of Sweden (A & B); healthcare professionals at antenatal units and in family counselling in a county within the south-west of Sweden (C); expecting and new parents in all of Sweden (D)

What does the study involve?

This is an intervention study that includes exploration of two different serious games: (1) Childbirth Journey, and (2) Interplay. The study includes four different sub-studies (A-D) with both qualitative and quantitative methods and longitudinal design.

What are the possible benefits and risks o participating?

Interventions included in this study are considered low-risk. A few expected negative experiences for the participants may become relevant. These may relate to usage of the serious games, problematic experiences with the technology, negative feelings about one's couple relationship with the partner (study B & D), or insufficient support for the upcoming labor and parenthood. The use of the applications may, on the other hand, lead to positive effects to participants' feelings of being able to handle childbirth, parenthood or their relationship with their partner (study A, B & D). For example, expecting parents may perceive the interventions (the Childbirth Journey and Interplay) as trustworthy since they are controlled and provided by healthcare professionals. Negative side effects such as disappointment with participant dropouts are to be examined and the researchers will assess the experiences of the participants.

Where does the study run from? University of Skövde (Sweden)

When is the study starting and how long is it expected to run for? March 2020 to December 2024

Who is funding the study? University of Skövde (Sweden)

Who is the main contact? RN, RM, PhD Caroline Bäckström caroline.backstrom@yahoo.se

Contact information

Type(s) Scientific

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Public

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 01/10/2020

Study information

Scientific Title

Digital tools as parental support – how should they be provided to meet the needs of expecting and new parents? An interventional study with both qualitative and quantitative methods and a longitudinal design

Study objectives

The objectives of the proposed study are to explore two different serious games: (1) the 'Childbirth Journey' (Swedish: 'Förlossningsresan') relating to pregnancy, childbirth and parenthood; and (2) 'Interplay' (Swedish: 'Samspel') relating to parental couple relationship and parenthood, as well as to:

1. Explore parents' experiences from and user behavior in Childbirth Journey (Study A).

2. Explore parents' experiences from and user behavior in Interplay (Study B).

3. Explore healthcare professionals' experiences in Childbirth Journey and Interplay (Study C).

4. Explore parents' user behavior over time and individual sessions in Interplay, as well as associated factors between parents' user behavior and experiences from Interplay and their perceived quality of parental couple relationship, social support, and sense of coherence (Study D).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/06/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2020-01689

Study design

Interventional study that includes four different sub-studies (A-D) with both qualitative and quantitative methods and longitudinal design

Primary study design

Observational

Secondary study design

Explorative design and prospective longitudinal design for quantitative methods

Study setting(s) Community

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Sense of coherence, perceived quality of parental couple relationship, social support

Interventions

For the interventions, two different serious games are to be explored: (1) Childbirth Journey, and (2) Interplay. All participants will receive one of the two serious games, depending on which part of the study they participate within. Participants within study A and C will receive the Childbirth Journey and participants within study B, C and D will receive Interplay. For the proposed study, the researchers will collect data through interviews (A-C) as well as repeated web-based questionnaires (D). Interviews will be held when the participants have had access to the intervention (the Childbirth Journey or Interplay) for approximately 2 weeks. Within study D, participants will complete a web-based questionnaire at baseline (Q1), before receiving the intervention. Another web-based questionnaire (Q2) will be sent to the participants 6 months after Q1.

Intervention Type

Other

Primary outcome measure

Qualitative outcomes (study A-C):

1. Parents' experiences from and user behaviour in Childbirth Journey (A)

2. Parents' experiences from and user behaviour in Interplay (B)

3. Healthcare professionals' experiences in Childbirth Journey and Interplay (C)

Qualitative data from interviews with parents and professionals will be collected two weeks after they received the intervention. The qualitative data from interviews with parents and professionals will be

analyzed using phenomenography (Sjöström & Dahlgren, 2002) and content analysis (Graneheim, Lindgren, & Lundman, 2017).

Quantitative outcomes (study D) collected at baseline (T1) and six months after (T2):

1. Sense of coherence measured using the SOC-13

2. Social support measured using the Multidimensional Perceived Social Support Scale (MSPSS)

3. Quality of the parental couple relationship measured using the Quality of dyadic relationship scale QDR 36

Secondary outcome measures

There are no secondary outcome measures

Overall study start date 01/03/2020

Completion date 21/12/2024

Eligibility

Key inclusion criteria

1. Expecting and new parents within the study setting (A & B)

2. Healthcare professionals at antenatal units and within family counselling within the study setting (C)

3. Expecting and new parents within Sweden (D)

Participant type(s) Mixed

Age group

Adult

Sex Both

Target number of participants

The researchers plan to include between 10 and 20 parents in study A and B each. In study C, between 10 and 15 healthcare professionals will be recruited. In study D, about 100 parents will be recruited.

Key exclusion criteria

1. Parents with a lack of ability in speaking, reading or understanding Swedish (B & D) or English language (A)

2. Parents or healthcare professionals who do not have access to mobile phones that enable the digital parental support to be used (B & C: Intervention Interplay & D)

3. Parents or professionals with severe visual impairment or other physical disorder that would prevent them to use touch feature on mobile phones (B & C: Intervention Interplay & D)

4. Single parents or parental couples in which only one of the parents agrees to participate (B & D)

Date of first enrolment

01/06/2020

Date of final enrolment 31/12/2023

Locations

Countries of recruitment Sweden **Study participating centre Skaraborg Hospital Skövde** Labor and postnatal ward BB-Skövde Skövde Sweden 54128

Sponsor information

Organisation University of Skövde

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Sponsor type University/education

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ROR https://ror.org/051mrsz47

Funder(s)

Funder type University/education

Funder Name Högskolan i Skövde

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

21/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of permission.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		24/11/2021	14/12/2021	Yes	No