

Design and evaluation of the StartingTogether App for preventive child health care

Submission date 09/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/09/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The StartingTogether program (SamenStarten in Dutch) is a method used for preventive youth health care in the Netherlands. It can help with the early identification of social-emotional and behavioural problems in young children. Despite this program, nurses in preventive child health care find it challenging to determine these family issues and need for care. Also, they find it challenging to provide education, refer to social services, and increase parent empowerment. To help overcome these challenges, the StartingTogether App has been developed, offering nurses and parents conversational support, tailored education and information on social services. The aim of this study is to evaluate the effectiveness of the StartingTogether App when used during home visits.

Who can participate?

Nurses who work for the preventive youth health care in Amsterdam, the Netherlands

What does the study involve?

Nurses make home visits to parents and are randomly allocated to either use the app or to provide care as usual. Nurses complete surveys on the challenges experienced during visits. Parents are invited to complete surveys on their satisfaction with health care and the app. Nurses are interviewed on the benefits of and barriers to using the app.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

GGD Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?

January 2012 to October 2013

Who is funding the study?

Netherlands Organisation for Health Research and Development

Who is the main contact?
Dr Olivier Blanson Henkemans

Contact information

Type(s)
Scientific

Contact name
Dr Olivier Blanson Henkemans

ORCID ID
<http://orcid.org/0000-0002-8931-9207>

Contact details
Schipholweg 77
Leiden
Netherlands
2316 ZL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TNO-5101117

Study information

Scientific Title
Design and evaluation of the StartingTogether App for home visits in preventive child health care

Acronym
StartingTogether App

Study objectives
The main research questions for the qualitative study, were: What needs do nurses and parents have, with regard to the home visits? How can the ST App be applied during home visits, so as to contribute to patient-centred quality of care? What issues are important for further implementation? To answer these questions, the trialists conducted: 1) a needs assessment; 2) a pilot test; 3) a process evaluation during the iterative development of the app; and 4) an assessment for future use.

The second part of the study consisted of a Randomized Controlled Trial (RCT), to evaluate the effectiveness of the ST App when applied during home visits. The main research questions for the quantitative study, to measure the effectiveness were: a) how satisfied are nurses' and

parents' with the home visit; b) how do they rate the usability of the app; and c) what is the proportion of valid referrals made after the home visit?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics committee of TNO (Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek [Netherlands Organisation for Applied Scientific Research]), 05/07/2012, ref: 05101117

Study design

Exploratory sequential mixed method design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

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

Preventive child health care

Interventions

An exploratory sequential mixed method design was used, in which the qualitative study is combined with the quantitative (Creswell, 2009). The value of this design exists in the fact that results are enhanced to a greater level than the quantitative or qualitative component on their own, and that the approach allows for development and evaluation of the app at the same time. The first part of the study consisted of a qualitative, formative evaluation of the ST App, with the aim of improving its design and implementation. The second part of the study consisted of a Randomized Controlled Trial (RCT), to evaluate the effectiveness of the ST App when applied during home visits.

The RCT was conducted over a period of one year (October 2012 through September 2013). A teams of nurses were assigned to the intervention group (STA), who made home visits with the StartingTogether App (ST App) or the control group, who made home visits as usual (CAU). The trialists applied a stratified randomization method: four teams were allocated to the intervention group (N=16) and five teams were allocated to the control group (N=17). All participating nurses received a two-hour training to complete the survey and administer it to the parents. The STA nurses received a four-hour training to use the ST App, covering a theoretical and practical module.

The intervention consisted of the StartingTogether App (ST App), offering textual and visual conversational support for nurses and parents and tailored education and information on social services. The first function of the ST App: textual and visual conversational support for nurses and parents. The parents first select one or more pictograms (e.g., sleeping child or a couple with a heart) that illustrate the topic(s) they want to discuss with the nurse, eliciting a conversation about their family situation (e.g., the babies' sleeping rhythm, or the relationship with their partner). Then, they value these issues with the use of emoticons (i.e., sad/happy, angry/calm, insecure/secure, and shameful/proud). Parents can rate their current emotional state on a scale from 1 through 10 (e.g., 4, somewhat sad), define their goal state (e.g., 5 or 6, somewhat happy) and determine their personal needs. These ratings are meant to promote self-reflection, prioritization of their needs and self-activation. Also, they can determine what they can do themselves, with the help of their social environment, to achieve this goal state.

The concept of selecting and discussing pictograms is derived from context mapping. This technique consists of people selecting and discussing artefacts (in this case pictograms) and to make their tacit experiences and feelings explicit (Sleeswijk Visser et al., 2005). This approach can aid parents and nurses to understand the bidirectional influences between their contexts and their child's development. Also, it can aid them to talk about sensitive topics, which is known to be a barrier for nurse-parent interaction (Regber et al., 2013). The valuing of the pictograms stems from both context mapping and solution focused (brief) therapy (SFBT). In SFBT, through precisely constructed questions about the family situation, parents can focus on identifying their goals and generating a detailed description of what life will be like when the goal is accomplished (Kim, 2008). Thus, the focus lies on constructing situations in which the problem is resolved rather than solving problems.

The app provides educational materials (i.e. websites, flyers and videos), and lists social services in the community, tailored to the family's situation, need and living location. Examples are an educational video on shaken baby syndrome, pamphlets on upbringing and websites with self-management programs for parents with psychological problems. The educational materials and social services in the community were provided and reviewed by the nurses and team leaders, and added to the app by the researcher, before and during the study. The DMO-p domains are used to guide the selection of relevant materials, tailored to the social-emotional and behavioural development of the child. The nurse selects one or more domains, based on the parents' selection of topics and evaluation of their family situation. Earlier research has shown that tailoring can enhance the users' participation and engagement in the intervention and, in turn, patient empowerment (i.e., knowledge and skills for self-management) (Lustria et al., 2010). After choosing one or more domains, the app provides relevant education and social services in the community. The parents and nurse can browse through these services and compare them; who is the target group, what is the service, how much does it cost and is it in the neighbourhood? The locations of the services in the community are displayed on a map, showing the current (home) location and the locations of the selected service. This is meant to facilitate shared decision-making about which care will be provided, which can contribute to parent empowerment, as well as to the parents' satisfaction in regard to the home visit (Suh & Lee, 2010).

The app keeps a record of the home visit, which is sent by email to the parent at the end of the visit. The report covers the family's situation and evaluation, the selected educational materials and information about social services (with contact details), notes and follow-up appointments. With the parent's consent, the nurse can send the email to him- or herself, for future reference.

For privacy purposes, once the email is sent, the app is cleared from all content. Finally, the app offers tools for the nurse, such as official websites for PCH-professionals on youth and upbringing. Here, they can access the relevant care standards for preparation of the home visit.

Intervention Type

Device

Primary outcome measure

1. Nurses' satisfaction with the home visit, measured through a survey administered to the nurse on known challenges experienced during StartingTogether home visits (items with a 5-point Likert scale) after each home visit during the trial period
2. Parents' satisfaction with the home visit, measured through a survey with items of the 'CQ-Index JGZ' administered to the parent (items with a 5-point Likert scale) and one item evaluating the visit overall (10-point scale) after each home visit during the trial period
3. Parents' rating of the usability of the app, measured after each home visit during the trial period through a survey administered to the parents in the intervention group, with one item evaluating the app's usability (5-point scale)
4. The proportion of valid referrals made after the home visit, measured through dossier audit at the end of the trial

Secondary outcome measures

1. Demographics of the nurses, measured through a survey administered to the nurse at baseline
2. Demographics of children and parents, measured through a survey administered to the parent after each home visit during the trial period

Overall study start date

01/01/2012

Completion date

01/10/2013

Eligibility

Key inclusion criteria

1. Preventive health care (PHC) nurses in Amsterdam and working in one of the teams participating in the study
2. Written consent to participate in the study

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

16 participants per study group

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/2012

Date of final enrolment

01/03/2013

Locations**Countries of recruitment**

Netherlands

Netherlands Antilles

Study participating centre**GGD Amsterdam**

Nieuwe Achtergracht 100

Amsterdam

Netherlands

1018 WT

Sponsor information**Organisation**

TNO

Sponsor details

Anna van Buerenplein 1

The Hague

Netherlands

2595 DA

+31 (0)88 866 0000

wegwijzer@tno.nl

Sponsor type

Research organisation

Website

www.tno.nl

ROR

<https://ror.org/01bnjb948>

Funder(s)

Funder type

Government

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

The trialists intend to publish an article in BMC Nursing on the results.

Intention to publish date

01/11/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Olivier Blanson Henkemans. The data originate from administered surveys and conducted audit and are saved in an Excel file (demographics nurses) and SPSS files (demographics participating families and trial data, including audit data). The data is available after formalities, for the period needed to conduct proposed analyses, with a maximum of six months. Data will be shared through a secured FTP connection with organisations in the field of (preventive youth) health research and/or digital health innovations (eHealth). Data can be used for the combination of the results of multiple scientific studies, such as a meta-analysis, using data analysis programs, such as SPSS and R. Informed consent of nurses and parents are obtained to use data for scientific purposes. The dataset is pseudo-anonymized, as it contains demographic data on participating nurses and families. Before exchanging the data, TNO and requesting party will sign a 'Data Processing Agreement', drawn up by TNO.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No