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A gamified mobile health intervention for children in day surgery care: Protocol for a randomized controlled trial

Arja Rantala[1] | Anna-Leena Vuorinen[2] | Jonna Koivisto[3] | Heidi Similä[4] |
Otto Helve[5,6] | Pekka Lahdenne[7] | Minna Pikkarainen[4,8,9] | Kadri Haljas[10] |
Tarja Pölkki[1]

[1]Research Unit of Nursing Science and Health Management, Faculty of Medicine, University of Oulu, Oulu, Finland

[2]VTT Technical Research Centre of Finland, Tampere, Finland

[3]Faculty of Information Technology and Communication Sciences, Tampere University, Tampere, Finland

[4]VTT Technical Research Centre of Finland, Oulu, Finland

[5]Clinicum, University of Helsinki, Helsinki, Finland

[6]Pediatric Research Center, Department of Pediatrics, Helsinki University Hospital, Helsinki, Finland

[7]Department of Pediatrics, Helsinki University Hospital, Helsinki, Finland

[8]Research Group of Medical Imaging, Physics and Technology, University of Oulu, Oulu, Finland

[9]Martti Ahtisaari Institute, Oulu Business School, Oulu University, Oulu, Finland

[10]Triumf Research OU, Tartu, Estonia

Correspondence
Arja Rantala, Research Unit of Nursing Science and Health Management, Faculty of Medicine, University of Oulu, Oulu, Finland.
Email: arja.rantala@oulu.fi

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Abstract

Aims: To describe a study protocol for a randomized controlled trial which will evaluate the effectiveness of a gamified mobile health intervention for children in whole day surgery care.

Design: A study protocol for a two-arm randomized controlled trial.

Methods: Participants will be randomly assigned to the intervention group ($N = 62$), in which patients receive routine care and play a mobile game designed for children or the control group ($N = 62$), in which patients receive routine care, including a mobile phone application that supports parents during the care path. The primary outcome is children's pre-operative anxiety, while the secondary outcome measures included fear and postoperative pain, along with parental satisfaction and anxiety. Data collection started in August 2020.

Results: The results of the ongoing randomized controlled trial will determine whether the developed gamified mobile health intervention can be recommended for hospital use, and whether it could be used to educate children about their surgical treatment to decrease anxiety.

1 | INTRODUCTION

Approximately 3–10 percent of children 7–12 years old in the United States and Europe receive outpatient treatment each year (Eurostat, 2019; Omling et al., 2018; Witt et al., 2016). Paediatric surgery is an unpleasant situation for parents as it may cause anxiety (Landier et al., 2018), and has also been reported to cause fear and anxiety among children (Chorney & Kain, 2009; Kain et al., 1996; Witt et al., 2016). Children need to be able to cope with the treatment they will receive. Distraction tools are one way to draw children's attention to something else when they are facing a painful or scary situation (Koller & Goldman, 2012).

After an operation, children might suffer from pain for days or weeks (Lao et al., 2020), and parents need information concerning the medicine their children are taking, along with any possible side effects (Rantala et al., 2020). Pain management is important for postsurgical care, and relevant in the context of paediatric surgery because children might suffer from behavioural problems and eating difficulties after their surgery (Power et al., 2012). However, pain among children who have undergone surgery is still underestimated and poorly managed (Craig, 2020; Dorkham et al., 2014), as some children may be surprised by the amount of postoperative pain (Friedrichsdorf & Goubert, 2019; Sutters et al., 2007). Nevertheless, knowledge about interventions for managing acute pain among children has increased in recent years (Caes et al., 2016; Friedrichsdorf & Goubert, 2019). Another important aspect of postoperative care is that parents face difficulties getting their children to clearly explain the pain they are in (Dorkham et al., 2014; Quaye et al., 2019). Innovative mobile health interventions could be crucial in enhancing children's involvement in their own care.

2 | BACKGROUND

Mobile health (mHealth) solutions have the potential (Ryu, 2012) to increase children's commitment to their health issues (Fedele et al., 2017; Ryu, 2012). However, parents and in some cases children, need to be provided with written information concerning the pre-, intra- and postoperative phases of the treatment to enhance their knowledge (Landier et al., 2018). The information should be in the person's own language (Rantala, Pikkarainen, & Pölkki, 2020) and, when provided to children, based on their age and understanding (EACH, 2016; Quaye et al., 2019). Several mHealth studies describe the development of web-based games that prepare children for their surgery (Buffel et al., 2019; Chow et al., 2017), with several examples of approaches using virtual reality (Al-Nerabieah et al., 2020; Jung et al., 2021). Furthermore, additional web-based interventions

aiming to reduce anxiety before treatment have been developed with both children and family members (Fortier et al., 2015; Wright et al., 2020). In addition, Kwan et al. (2016) focused on the intraoperative setting and designed an approach in which parental anxiety can be reduced by the sending of informative SMS messages throughout their children's ongoing surgery (Kwan et al., 2016).

In the postoperative setting, children use non-pharmacological methods like distraction – along with medicine – for pain relief (Pölkki et al., 2003). Prior research has presented web-based games designed to distract children from feeling pain yet have not shown evidence for the statistically significant effectiveness of these approaches for managing postoperative pain (Buffel et al., 2019). Virtual reality has been found to be effective at relieving pain in painful procedures, for example venipuncture (Bergomi et al., 2018; Chan et al., 2019). On the other hand, a systematic review and meta-analysis (Rantala et al., 2020) showed that web-based mobile health interventions, including video clips, web-based treatment preparation interventions and games, can reduce children's pre-operative anxiety and increase parental satisfaction, but did not report whether these approaches were effective at reducing children's pain after day surgery treatment. According to Rantala, Pikkarainen, and Pölkki (2020), health care personnel could integrate gamification into the patient journey with the objective of increasing patients' commitment to their treatment and enabling communication between personnel and patients before a hospital visit (Rantala, Pikkarainen, & Pölkki, 2020). Considering the parent's view, a digital gamified solution should support the care of children, prepare both parents and children for the upcoming treatment and increase children's commitment to care (Rantala, Jansson, et al., 2020). An mHealth intervention utilizing gamification can be given as an easy-to-use information tool for children and family (Edwards et al., 2016) beforehand to decrease both the families' and children's stress and anxiety (Rantala, Pikkarainen, Miettunen, et al., 2020; Tark et al., 2019) while increasing children's cooperation with health personnel (Rantala, Jansson, et al., 2020; Wantanakorn et al., 2018). Gamification can increase children's adherence to their own treatment (Edwards et al., 2016; Tark et al., 2019), whereas intra- and postoperative setting mHealth and gamification can increase children's immersion and be used as a distractor in a painful situation (Rantala, Pikkarainen, & Pölkki, 2020; Wantanakorn et al., 2018). In addition, having a pain scale in mobile form is useful for family and health personnel (Sun et al., 2015). An Mhealth intervention can be used as a type of postoperative information and cooperation, medication notification (Li et al., 2019; Rantala, Pikkarainen, & Pölkki, 2020) and emergency information tool for family (Ehrler et al., 2017).

To the best of our knowledge, no randomized, controlled studies have as of yet focused on the paediatric care path from pre-operative to postoperative setting. This paper presents a study protocol for a

randomized controlled trial (RCT) that evaluates the effectiveness of a gamified mobile health intervention designed to reduce children's anxiety, fear and pain in surgery care situations. The RCT protocol is part of the ICory project, in which we co-created a unique patient journey solution (i.e. the ICory-solution) for parents and children that covers the entire outpatient journey – from home to hospital and back home.

The purpose of this paper is to describe a study protocol for an ongoing, two-armed RCT which is being conducted to evaluate the effectiveness of a gamified mobile health intervention for children. The intervention encompasses a gamified solution that children can access on their own mobile phone. We hypothesize that children in the intervention group will experience less anxiety and fear before day surgery and will feel less postsurgical pain than children in the control group. In addition, we hypothesize that parents of children in the intervention group will be more satisfied with the care, and less anxious prior to the surgery, than the parents whose children are in the control group.

3 | THE STUDY

3.1 | Study design and setting

The presented protocol describes a single-site, single-blind, parallel-arm RCT with two study arms (Figure 1). The study will be conducted at a 140-bed tertiary care paediatric hospital in Finland. The university hospital provides specialized paediatric, paediatric surgery, child neurology and child psychiatry services. In 2019, a total of 6,883 surgical operations, of which 3,300 were day surgery procedures, were performed at the hospital. The study has been designed according to the guidelines of the CONSORT-EHEALTH statement (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and onLine TeleHealth; Eysenbach, 2011). This protocol was prepared in accordance with the SPIRIT 2013 statement (Chan et al., 2013).

4 | METHODS

4.1 | Participants

This study focuses on children undergoing a day surgery. The inclusion and exclusion criteria are presented in Table 1. The potential participants will be screened by a research nurse using the hospital treatment queue. The research nurse will first assess the age of the child and his/her diagnosis code(s). If found eligible, the family will be contacted. Families that indicate their willingness to participate will be further asked about child's ability to read, his/her access to a smart phone and chronic illnesses and/or pain and possible cognitive and learning disabilities. Once recruited, the corresponding author will contact the family again and discuss with the child about the study. If the child agrees to participate, (s)he will be randomly

assigned along with their respective parents/legal guardian, to either the intervention or control group. In this study, considering all family types, children may have two parents or a single parent/legal guardian. Recruitment started in August 2020.

4.2 | Ethical considerations and trial registration

The study has been approved by the ethics committee (Ref. no 180/2020). The RCT has been registered at ClinicalTrials.gov: NCT04277299. All of the participants will understand that taking part in the research is voluntary. Children between 7–9 years and 10–12 years of age will receive separate information sheets and consent forms which have been carefully drafted considering their age and understanding (EACH, 2016). Children will have the possibility to ask the research nurse and/or corresponding author questions about the research before giving their consent. Parents will also get the information sheet and give consent for their child to participate in the research. Following parental consent, the research nurse will have access to the children's patient information in the hospital so that they will have accurate medication information during the outpatient treatment. Paper/printed materials will be stored in a locked filing cabinet. The audio material and files will be destroyed after the data have been analysed. The data will be stored for 5 years in archived format according to relevant legislation GDPR 2018 (European Parliament & Council of European Union, 2016). Permission to use certain validated instruments has been requested from the original researchers, and the instruments have been translated into Finnish and pretested with children between 4 and 14 years old ($n = 9$) before the RCT.

4.3 | Sample size

According to Cumino et al. (2017), approximately 75% of children feel pre-operative anxiety. We anticipated that the gamified mobile health intervention could reduce this proportion of children to 40%. A Fisher's exact test – applying a two-sided alpha value of 0.05 and 80% power – estimated that 74 participants are required for the study. According to previous studies, attrition rates in postoperative settings vary from 12%–60% (Kim et al., 2015; Marechal et al., 2017; Seiden et al., 2014; Stewart et al., 2018). For this study, we assumed a dropout rate of 40%; thus, the sample size required to ensure adequate statistical power increased to 124 (62 + 62) children.

4.4 | Randomization and blinding

The participants will be randomized using stratified block randomization; children will first be stratified by age (7–9 or 10–12 years of age), and then randomized in permuted blocks using block sizes of 2, 4 and 6. The various block sizes are used to ensure unpredictability of group allocation as the primary outcome is assessed by the
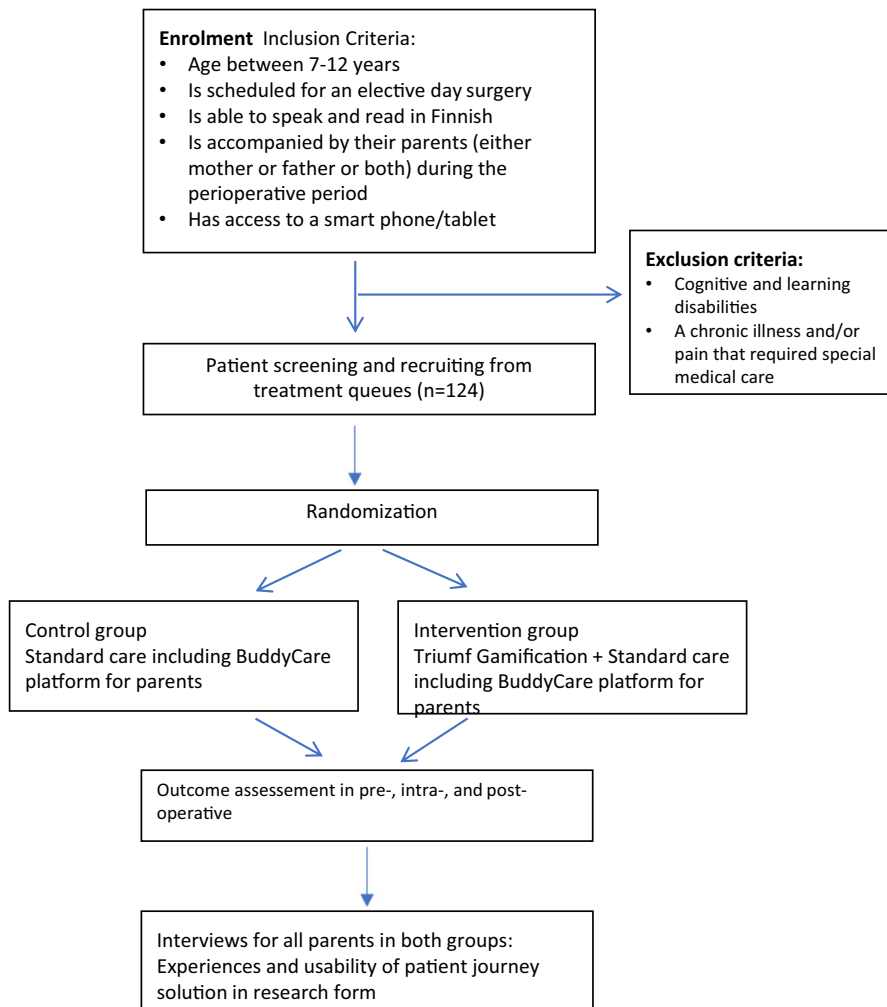
Enrolment Inclusion Criteria:
• Age between 7-12 years
• Is scheduled for an elective day surgery
• Is able to speak and read in Finnish
• Is accompanied by their parents (either mother or father or both) during the perioperative period
• Has access to a smart phone/tablet

Exclusion criteria:
• Cognitive and learning disabilities
• A chronic illness and/or pain that required special medical care

Patient screening and recruiting from treatment queues (n=124)

Randomization

Control group
Standard care including BuddyCare platform for parents

Intervention group
Triumf Gamification + Standard care including BuddyCare platform for parents

Outcome assessement in pre-, intra-, and post-operative

Interviews for all parents in both groups: Experiences and usability of patient journey solution in research form

TABLE 1 Inclusion and exclusion criteria for children

Inclusion	Exclusion
Age between 7–12 years	Cognitive and learning disabilities
Scheduled for an elective day surgery	Chronic illness and/or pain that required special medical care
Able to speak and read in Finnish	
Accompanied by their parents (either mother or father or both) during the perioperative period	
Children has access to a smart phone/tablet	

research nurse. The allocation ratio is 1:1. The allocation sequence will be concealed using opaque and sealed envelopes until both children and parents have given their consent. The research nurse will be blinded to group assignment for the entire study. In addition, the outcome assessors will not know which child has been allocated to which group. Due to the nature of the research, blinding will not be possible for the participants (children and parents). All of the children who will participate in the study will have their own mobile phone; thus, we consider the use of mobile phones a minimum risk for contamination.

The research nurse will send each child a personal code which is entered upon downloading the mobile application. Each parent

has their own code. Children in the intervention group will receive instructions from the corresponding author about how to download the gamified mobile health application, that is Triumf game, from the Play Store. Every child has their own code and will use their own email address, or an email address created specifically for the study. The Triumf game will not collect any personal information about the children. Parents will get the patient journey solution, which will request them to answer certain measures and collect demographic information about children and their parents. Children will play the game in pre-, intra- and postoperative settings, and then respond to the measures on their parents' mobile phone.

4.5 | The intervention

The participants in the intervention group will receive routine care – including the parental journey solution – which is the current practice at the study hospital. The intervention has two components: (a) the Buddy Healthcare's mobile application (BuddyCare), which is a mobile patient journey solution that gives a comprehensive, day-by-day perioperative guide for parents about their child's surgery and includes an interface through which health care professionals can monitor parents' and their children's needs (Figure 2); and (b) the Triumf gamified mobile health intervention that gives emotional support, pre-operative preparation information and distraction for children (Figure 3).

Triumf includes a novel platform that is deployed as a digital intervention to reach out to paediatric patients through a game environment. The solution delivers digital therapeutics through a mobile game environment. Digital therapeutics (DTx) is defined as evidence-based, clinically evaluated therapeutic interventions delivered through software (Digital Therapeutic Product, 2020). The solution was primarily developed to improve the mental well-being and quality of life of children and early adolescents (7–14 years of age). The platform has been co-designed with children with and without health issues, their parents and care teams from Finland and Estonia to develop a solution that has a maximum impact and is universally applicable to burdening factors. The game environment provides a medium for delivering comprehensive care that is familiar, safe and intuitive to children. This is an important characteristic of user-centred digital solutions and is central to the methodology for
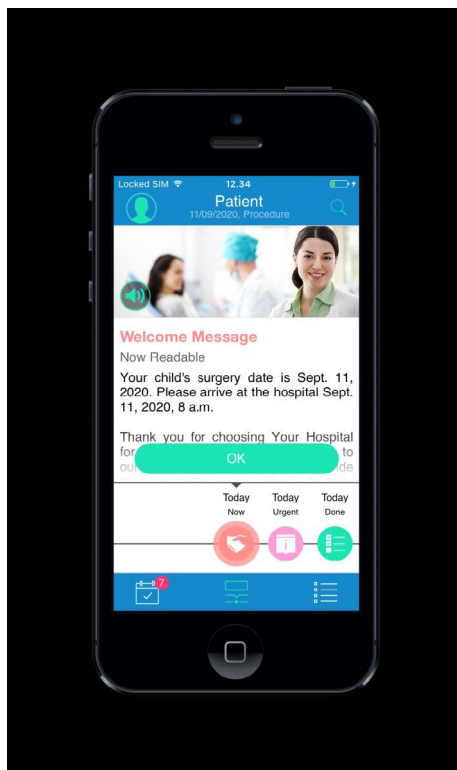

FIGURE 2 Buddy care solution for parental use

creating patient-centred healthcare services (Bechtel & Ness, 2010; Yardley et al., 2015). The DTx platform Triumf combines psychosocial research, validated psychological techniques and data analytics to assess, monitor and support the mental health of children. The solution also induces the creation of healthy habits during gameplay. Unlike most other commercially available digital health solutions, Triumf is based on the self-determination theory of motivation and behaviour change (Ryan & Deci, 2000). In the solution, children need to save Triumfland city from the Disease Monster. During gameplay, children will put emotions, their coping ability, problem-solving, activity-based learning, behaviour change techniques and psychotherapeutic methodologies to practical use. A multi-site clinical study among paediatric cancer patients showed that using the Triumf game as a digital intervention can improve mental well-being and boost user engagement (Tark, 2019; Tark et al., 2019). The game environment enables delivering research-based content to educate, monitor and support children in a personalized manner, with the underlying objectives of: (a) helping children to better understand their upcoming treatment; (b) offering external support than can promote internal motivation to cope with the treatment; (c) providing children with cognitive challenges and distraction, along with activity-based learning of healthy behaviours; (d) continuously monitoring the psychological well-being of children to offer relevant, and personalized, psychoeducation and coping techniques. These objectives will ultimately support the formation of better self-understanding and constructive health behaviours, such as physical activity and diet. Furthermore, the solution enabled children to take a virtual tour of the hospital – which was identified as a need in a previous study (Rantala, Pikkarainen, & Pölkki, 2020).

Only the tutorial of the game – during which children are guided through the game narrative – follows a predetermined structure. Subsequent gameplay, that is the educational module and other elements of the intervention, is determined by in-game choices made by the player. Furthermore, provision of psychological support depends on the individual emotional state of the patient. The intervention also includes several mini-games, for example games related to the application of information learned within the game, cognitive challenges and entertainment games that offer cognitive distraction.

Children are advised to engage with the Triumf game on their own smart device for 2–4 weeks before the treatment and 1–2 weeks after the operation. BuddyCare is available for parents to download onto their own mobile phone. Children in the control group will receive routine care given by the hospital, which consists of a doctor consultation, pre-operative preparation and postoperative care, while the parents are supported by the BuddyCare mobile application – which is currently the standard routine at this hospital.

4.6 | Standard care

Children who may require surgery are referred to the New Children's Hospital for paediatric surgical consultation. The need for surgical treatment – including the procedure and schedule – is then decided
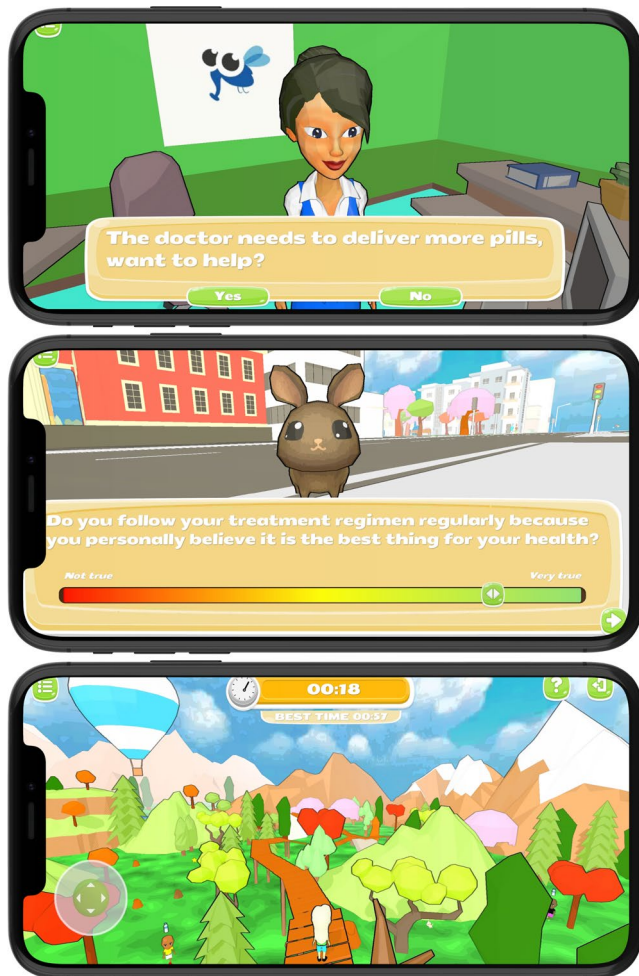
FIGURE 3 TriumfHealth, the gamified mobile health intervention for children in the intervention group

by the paediatric surgeon. During the appointment, the parents and child will receive primary information concerning the procedure in the day surgery unit once the need for surgery has been identified

and discussed. A part of the current standard of care is providing information on the BuddyCare mobile application, which contains all the necessary instructions concerning the procedure. The family and nursing staff will mainly communicate through the app, for example reminders about the time of the procedure and details of how the child and parents should prepare for the procedure are delivered via the app. Upon admission to the hospital, the parents are allowed to follow the child to the operating theatre and remain there until the child falls asleep. Routinely, no premedication is used. Once the procedure has been completed, the child is transferred to the recovery space where the parents are invited once the child has woken up. Staff will check that the parents and child understand the instructions for home care before the child is discharged. The family and nursing staff will communicate about postoperative pain through BuddyCare.

4.7 | Data collection methods

The data used in the presented RCT will be collected digitally using BuddyCare. This data collection method has been specifically developed for this study and has not been used previously. Only information about the study and consent from children and parents are given in paper form. The outcome data will include: (a) responses to questionnaires concerning the patient journey solution; and (b) data from medical records concerning premedication and analgesic. Measurements will be conducted during the pre-, intra- and postoperative phases (Table 2). Parents will download the patient journey solution 2–4 weeks before children's treatment and provide their demographic information at this time point. The parents will continuously provide information to the application from 1 day before the surgery to 10 days after treatment using patient-reported measures. The research nurse will enter the patient's medication information and assess children's anxiety to the solution. Parents will get push notifications about when the assessment should be done, and reminders will follow if they did not complete the assessment in the right time frame (Table 2).

TABLE 2 Intervention and data collection schedule

Time point	At home 2–4 weeks before surgery	At home 1 day before surgery	At hospital before treatment	During induction before anesthesia
Demographics of children and parents Previous hospital experience of children Used medication	x			
mYPAS			x	x
CPMAS		x	x	
Modified Pain scale (NRS, VAS and Faces Pain Scale)				
Premedication and analgesic by research nurse				
Parental satisfaction (Likert 0–10)		x		
Parental STAI -Y			x	
GAMEFULQUEST (simplified and shortened for children) for children in the intervention group (Likert 1–7)				

Abbreviations: CPMAS, Children's Perioperative Multidimensional Anxiety; mYPAS, The modified Yale Preoperative Anxiety Scale; NRS, Numeral Rating Scale; VAS, Visual Analogue Scale.

5 | OUTCOME ASSESSMENTS

5.1 | Background information

Information about children's age, gender, treatment in question, previous diseases, regular medication, allergies, previous surgical experiences and previous experiences from hospital will be collected. Parents will be asked for their age, gender, education and work status.

5.2 | Primary outcome

The primary outcome of the study is children's pre-operative anxiety, which will be measured with the modified Yale Preoperative Anxiety Scale (mYPAS) (Kain et al., 1995, 1997). mYPAS is a four-item scale (activity, vocalization, emotional expressivity, state of apparent arousal) and will be filled out by the research nurse. The total score ranges from 23–100, with higher scores reflecting higher levels of anxiety. A score of 31 and above indicates high anxiety. In the presented RCT, mYPAS has been translated into Finnish, tested by a research team ($n = 3$) including researchers and a research nurse, and pretested by the research nurse in a real hospital environment. The reliability and validity of this measure has been described in a previous study (Cohen's kappa 0.68–0.86; Intraclass Correlation Coefficient, ICC = 0.92; Kain et al., 1995; Skovby et al., 2014).

5.3 | Secondary outcomes

Children's perioperative anxiety and fear will also be assessed using the Children's Perioperative Multidimensional Anxiety Scale (CPMAS; Chow et al., 2016), which is an age-appropriate, self-reported measure of paediatric perioperative anxiety that has been validated for children between 7–13 years of age. The CPMAS is a visual analog scale (VAS) containing five items, each of which is scored from 0–100. The items are: Right now, how: (a) worried; (b) scared; (c) nervous are you?; along with (d) I feel that this might hurt and (e) I feel worried that something bad might happen. Higher scores indicate stronger feelings of anxiety and fear. The reliability and validity of this measure has been reported in previous studies (Cronbach's alpha ≥ 0.80, ICC = 0.71; Chow et al., 2016, 2017).

Children's postoperative pain will be evaluated with a modified Pain scale including Numerical Rating Scale (NRS), Verbal Rating Scale (VRS) and Faces Pain Scale in the same screen, when the children are able to rate their pain intensity by swiping their finger in the patient journey solution. In addition, the scale changes colour as the children are swiping their finger toward severe pain (Figure 4). The modified Pain scale is suitable for children at any ages and is based on previously validated pain assessment scales (Abu-Saad, 1984; von Baeyer & Spagrud, 2007).

Parental anxiety will be measured using the State-Trait Anxiety Inventory (STAI-Y), which is a psychological inventory consisting of 20 questions that parents self-assess using a four-point Likert scale (Spielberger, 1983, 2010). The STAI-Y demonstrated good reliability based on the earlier studies of Gustafson et al. (2020) (Cronbach's alpha; state = 0.93, trait = 0.92) and Bee Seok et al. (2018) (Cronbach's alpha; state = 0.92, trait = 0.92).

Parental satisfaction with the day surgery journey will be evaluated by a VAS ranging from 1–10, with 1 and 10 representing the lowest and highest levels of satisfaction, respectively.

The GAMEFULQUEST instrument measures the gameful experience associated with a game or gamified solution (Högberg et al., 2019). For the purposes of this study, a shortened and simplified version of the instrument has been created and will be used to measure how children in the intervention group perceived the gameful experience of the Triumf game. The simplified and shortened GAMEFULQUEST consists of 30 items concerning seven different dimensions of the gameful experience, namely, perceived achievement, challenge, competition, guidance, immersion, playfulness

In the recovery room	At home After treatment	At home Day 1 Post-treatment	At home Day 3 Post-treatment	At home Day 7 Post-treatment	At home day 10 Post-treatment
x					
x		x		x	
x		x	x	x	
x					
x	x				
x	x				
					x

FIGURE 4 Modified Pain Meter in BuddyCare solution

and sense of community (Högberg et al., 2019). The children will respond to the questions using a seven-point Likert scale (1 totally disagree–7 totally agree). The GAMEFULQUEST demonstrated good reliability and validity (Cronbach's alpha 0.87–0.92, convergent validity AVE ≥ 0.5) and the development and validation of the full GAMEFULQUEST measurement has been reported by Högberg et al. (2019).

Parental experiences of children's day surgery journey will be evaluated through a telephone interview conducted by a researcher two weeks after the child's treatment. Parents in both groups will be asked about their experiences with the digital children's day surgery care path and usefulness of the background information and measures in the parental journey solution. The interviews will be semi-structured (Kallio et al., 2016) with some modified questions about the usability of the solution (Brooke, 1996; Grym et al., 2019), here based on knowledge of a previous study (Rantala, Jansson, et al., 2020) and according to the pilot testing with two parents. The semi-structured interviews will contain questions such as the following: Could you please tell me how you have experienced going through your children's care path with your children with the help of BuddyCare? How clear was the device manual? (Response options from 1 = not clear at all to 5 = very clear) What parameters would

you like to add to the digital solution if you could choose whatever you wanted? The responsible researcher has experience conducting interviews.

The research nurse will evaluate the amount of medication (both premedication and analgesic) each child has received from their patient record.

5.4 | Data analysis

Data analysis will be performed according to the intention-to-treat (ITT) principle, that is children and parents will be analysed based on the arms to which they are originally allocated, regardless of the extent to which they use the application. The two study arms will be presented using descriptive statistics; more specifically, continuous variables will be presented using means and standard deviations or the median and interquartile range, whereas categorical variables will be presented as frequencies and percentages. Differences between the study arms will be analysed using appropriate statistical tests that account for the repeated measures design when necessary, and the results will be presented as a 95% confidence interval including the corresponding p-value. Conclusions of statistical significance are based on two-sided tests with a significance threshold of $p < .05$. Inference will be based on the effect and the 95% confidence interval including the p-value. Interviews will be analysed qualitatively using the principles of content analysis with research triangulation (Elo & Kyngäs, 2008; Polit & Beck, 2017).

5.5 | Data management

All of the participants will have their own study codes, which were created by an independent researcher who neither has access to BuddyCare nor any role in participant recruitment. These codes, which were placed in sealed envelopes, will be used to allocate participants to study arms. The research nurse and the corresponding author will use the codes. During the enrolment phase, the research nurse will enter the list of codes into an Excel table, which will be saved in a secure way. Only the research nurse and corresponding author will be allowed to use this information. The research nurse will get signed consent from children and their parents in paper form and will store these papers in a locked cabinet. The research nurse and corresponding author have access to BuddyCare. The principal investigator will change the treatment path of children in the intervention arm in BuddyCare by adding the Triumf game instruction. The research nurse will not see the study arms from BuddyCare. Data collected by BuddyCare will be stored in a secure cloud service in Europe, and the company providing this solution has signed a data processing agreement with the research partners who have joint controllership over the data. The data collected by BuddyCare will be pseudonymized by the service-providing company and delivered to a secure study server provided by the hospital for monitoring

and analysis by a limited group of researchers. The researchers will access the server using a virtual private network. Data from electronic health records will be collected and pseudonymized by the study nurse and stored on the secure study server provided by the hospital.

6 | DISCUSSION

Previous studies for children in her/his clinical pathway were designed only for pre - or intraoperative setting (Al-Nerabieah et al., 2020; Buffel et al., 2019; Chow et al.; 2017; Fortier et al., 2015; Jung et al., 2021; Kwan et al., 2016; Wright et al., 2020). In addition, the lack of interventions covering the whole pathway was shown in a systematic review of Rantala, Pikkarainen, Miettunen, et al. (2020). There is still a need for interventions that cover the whole paediatric patient surgical pathway, including pre-, intra- and postoperative settings. To the best of our knowledge, this paper describes the first RCT protocol for evaluating the effectiveness of a gamified mobile health intervention for children in the context of the entire paediatric surgery care path.

6.1 | Limitations

This section summarizes some limitation when setting up the study and collecting the data. To date, we have enrolled and randomized 40 patients (20 in the control group and 20 in the intervention group). In addition, the participating hospital implemented a new patient system at the end of October 2020, and this has significantly decreased the patient flow. In addition, the recruitment eventually began in August 2020, once schools had re-opened following summer vacation. The patients participating in the study are 7–12 years old, and at an early state of recruitment we quickly realized that many 7-year-old patients could not participate as they were unable to read.

The ongoing RCT has demonstrated that some participants have difficulties adhering to the protocol. For example, the parental journey solution includes numerous distinct measures, and some parents have not remembered to respond to these measures during the expected time window. Therefore, the principal investigator has begun to remind parents to respond to these measures on time; notably, the solution does not allow users to add information about pain retrospectively. The time windows for responding to the measures vary from measurement to measurement, and the initial results indicate that we have to assess whether these time windows are adequate for a majority of users.

Due to the nature of the intervention, it will be impossible to blind the children concerning which study arm they are allocated to. It is also important to note that although the research nurse will be blinded to the group assignment, blinding could be broken if the children discuss the intervention, or which study arm they belong

to, with the research nurse. In addition, a part of the outcomes used in the study are self-reported, which may affect the results if the participating children answer according to social expectations – that is consider what is the acceptable answer ('no pain' vs. 'pain') when responding. However, the study also includes objective measures within the same time frame.

Presumably, the child will recover quickly from the day surgery and return home on the same day. Our study will also consider the possibility that the child will have to remain in the hospital for observation. In this study, we will have heterogeneous types of surgeries in our study, which will affect the postoperative outcome (pain). In the selected hospital, we do not have many children aged 7–12 years old having the same type of surgery performed. However, we believe that children feel anxiety and fear beforehand, despite the type of treatment. Based on these criteria, there might be some limitations about the postoperative outcome.

7 | CONCLUSION

- This study protocol adheres to the SPIRIT guidelines for clinical trial protocols.
- If the solution is found to be effective at reducing children's anxiety and fear in the pre-operative setting, it could be used to educate children about their day surgery treatment so that they could be more comfortable without their parents.
- Moreover, if the solution is found to be effective at reducing children's pain after surgery, it could be used as a distraction tool in the postoperative setting and might reduce children's fears of hospitalization.
- In addition, the mobile health intervention could reduce the potentially untreated pain that has shown to exert both short- and long-term harmful effects on paediatric patients.
- Regarding parents, a solution that is effective at reducing parental anxiety and increasing parental satisfaction with their children´s outpatient surgery journey could be a valuable resource when preparing parents for their children's surgical procedure.
- Finally, the solution is also relevant from an organizational perspective, as a mobile health intervention that is useful to both parents and children could be cost-effective as it would save time in the counselling of paediatric patients and their parents.

CONFLICT OF INTERESTS

Author Dr. Kadri Haljas is an employee of company Triumf Health. No conflict of interest has been declared by the other authors.

AUTHOR CONTRIBUTIONS

AR and TP planned the work. AR, A-LV, JK, HS, OH, PK, MP, KH and TP made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work. AR, A-LV, JK, HS, OH, PK, MP, KH and TP drafted the work or revised it critically for important intellectual content. Each author have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Each author gave their final approval of the version to be published. TP supervised the work.

DATA AVAILABILITY STATEMENT

All data generated during this study are included in this published article.

ORCID

Arja Rantala [iD] https://orcid.org/0000-0003-0610-2107
Anna-Leena Vuorinen [iD] https://orcid.org/0000-0002-5658-1305
Jonna Koivisto [iD] https://orcid.org/0000-0002-6631-2571
Heidi Similä [iD] https://orcid.org/0000-0003-0241-1957
Otto Helve [iD] https://orcid.org/0000-0001-6254-3180
Pekka Lahdenne [iD] https://orcid.org/0000-0002-3983-2897
Minna Pikkarainen [iD] https://orcid.org/0000-0003-4516-6584
Kadri Haljas [iD] https://orcid.org/0000-0001-8725-1424
Tarja Pölkki [iD] https://orcid.org/0000-0002-8301-9537

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