

PARent EDucation and Counseling (PairEd-C) intervention to improve family-centered care: A Protocol for prospective acceptability study using Theoretical Framework of Acceptability.

Leul Deribe, Adamu Addissie, Eshetu Girma, Abdulkadir Gidey, Solomon Teferaa,
Nataliya Lindström

Submitted to: JMIR Research Protocols
on: November 28, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 21

..... 21

Figures 22

Figure 1..... 23

Figure 2..... 24

Figure 3..... 25

PARent EDucation and Counseling (PairEd-C) intervention to improve family-centered care: A Protocol for prospective acceptability study using Theoretical Framework of Acceptability.

Leul Deribe^{1*}; Adamu Addissie^{2*}; Eshetu Girma^{3*}; Abdulkadir Gidey^{4*}; Solomon Teferaa^{5*}; Nataliya Lindström^{6*}

¹School of Nursing and Midwifery College of health science Addis Ababa University Addis Ababa, Ethiopia ET

²School of Public Health College of health Science Addis Ababa University Addis Ababa ET

³School of Public Health college of health science Addis Ababa University Addis Ababa ET

⁴School of Medicine College of health science Addis Ababa University Addis Ababa ET

⁵School of Medicine College of health Science Addis Ababa University Addis Ababa ET

⁶Department of Applied Information Technology University of Gothenburg Goteborg SE

*these authors contributed equally

Corresponding Author:

Leul Deribe

School of Nursing and Midwifery

College of health science

Addis Ababa University

Tikur Anbessa Specialized Hospital

Addis Ababa, Ethiopia

Addis Ababa, Ethiopia

ET

Abstract

Background: Family-centered care (FCC) is an intervention approach that is based on respectful relationship between family and health care providers to ensure the health and well-being of children and their families. Even though health care providers have better perception regarding FCC, the level of its implementation was found to be low. Reasons for low implementation includes limited understanding, lack of training, lack of implementation guideline and tools to support its implementation. Thus, we developed parent education and counseling (PairEd-C) intervention to improve FCC in pediatric oncology setting and assess its acceptability.

Objective: The objective of this study is to assess prospective acceptability of parent education and counseling (PairEd-C) intervention using theoretical framework of acceptability (TFA) at pediatric oncology of tertiary hospital in Ethiopia.

Methods: The study will be conducted using exploratory qualitative study design. A total of 26 to 31 participants will be anticipated to be recruited for the in-depth interview. The study participants will be health service leaders working on child cancer, health care providers, social workers and parents of children with cancer. The study will assess acceptability of the PairEd-C intervention with the main components of providing training for health care team, providing education for parents, improving parents' capacity to attend, monitor and utilization of intervention, and arranging discussion among parents. Data will be analyzed using deductive thematic coding with a framework analysis technique based on the seven constructs of TFA. Atlas ti. Version 9 will be used to assist data analysis.

Results: Funding and ethical clearance for conducting the study was already obtained.

Conclusions: This acceptability study is expected to show as the designed intervention will be acceptable by study participant and we will obtain an important finding that will be used to improve the intervention before progressing to the next step of our project.

(JMIR Preprints 28/11/2023:54914)

DOI: <https://doi.org/10.2196/preprints.54914>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

✓ **Only make the preprint title and abstract visible.**

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/preprint/54914>

Original Manuscript

PARent EDucation and Counseling (PairEd-C) intervention to improve family-centered care: A Protocol for prospective acceptability study using Theoretical Framework of Acceptability.



Abstract

Background: Family-centered care (FCC) is an intervention approach based on a respectful relationship between family and healthcare providers to ensure the health and well-being of children and their families. Even though healthcare providers have a better perception of the FCC, the level of its implementation was found to be low. Reasons for low implementation include limited understanding, lack of training, and lack of implementation guidelines and tools to support its implementation. Thus, we developed parent education and counseling (PairEd-C) intervention to improve FCC in pediatric oncology settings and assess its acceptability.

Objective: The objective of this study is to assess the prospective acceptability of parent education and counseling (PairEd-C) intervention using the theoretical framework of acceptability (TFA) at pediatric oncology of tertiary hospital in Ethiopia.

Method: The study will be conducted using exploratory qualitative study design. A total of 10 to 15 participants will be anticipated to be recruited for the in-depth interview. The study participants will be health service leaders working on child cancer, health care providers, social workers, and parents of children with cancer. The intervention was developed using the integration of the first phase of the Medical Research Council MRC) for developing and testing complex interventions and the Behavior Change Wheel (BCW) framework. The main PairEd-C intervention components will align with the following intervention functions: education, persuasion, training, environmental restructuring, modeling, and enablement. These intervention functions were intended to improve FCC at the pediatric oncology unit through the provision of structured and comprehensive parental education and counseling for parents of children with cancer. The intervention will be implemented by providing training for the healthcare team, facilitating discussion among healthcare providers and setting a shared plan, improving the commitment of the healthcare team, providing education for parents, improving parents' capacity to attend the intervention sessions, arranging discussion among parents of children with cancer and provision of education and counseling on distress. The healthcare providers working in the unit will receive training on the designed intervention. The trained educators and the healthcare provider will deliver the intervention. Data will be analyzed using deductive thematic coding with a framework analysis technique based on the seven constructs of TFA. Atlas ti. version 9 will be used to assist in data analysis.

Result: Funding and ethical clearance for conducting the study were obtained.

Conclusion: This acceptability study is expected to show that the designed intervention will be acceptable to study participants, and we will obtain an important finding that will be used to improve the intervention before progressing to the next step of our project.

Introduction

Family-centered care (FCC) is a respectful relationship between family and healthcare providers to ensure the health and well-being of children and their families. It recognizes the abilities, customs, cultures, and knowledge that healthcare providers and families bring to the partnership. In addition to improving the patient and family's experience with healthcare, it lowers stress, fosters better communication, lessens conflict, and enhances the health of children with long-term medical disorders compared to parents received care without FCC, those received care based on FCC had improved psycho-social condition, communication with family members and health care professionals and understanding about childhood cancer [1]. Thus, the FCC provides care to children and families in which all family members are acknowledged as care recipients, and treatment is organized considering the family as a whole [2].

Although healthcare providers have better perception, there are disparities in performance and perceptions of various FCC sub-domains [3–9]. Different barriers that hinder the implementation of FCC related to health providers, organizations, and families were reported. These barriers include limited understanding of FCC principles, communication difficulties, inadequate skills, inconsistent training, and lack of knowledge, skills, time, or tools to support the implementation of FCC [8,10,11]. In addition, a lack of policy and guidelines on FCC, poor infrastructure, poor design quality, poor intervention content, and the burden of health providers from competing priorities were reported [12,13]. Shortage of healthcare providers, a lack of time, and the absence of the FCC system were also identified as barriers [10].

To overcome these challenges and facilitate the intervention of FCC in the study area, we designed a new intervention based on local context. For the development of this intervention, we identified evidence through a systematic review, explored the relevant and guiding theory for intervention development, conducted baseline studies using mixed methods, and held a series of FCC complex intervention designing workshops. Finally, we developed an intervention called Parent education and counseling (PairEd-C) to improve the delivery of FCC at the pediatric oncology unit in Ethiopia.

One key aspect of intervention effectiveness is the extent to which the intervention is considered acceptable to those providing and receiving it. Therefore, it is essential to conduct an acceptability study before implementing a new intervention [14]. Sekhon et al. define acceptability as “a multifaceted construct that reflects the extent to which people delivering or receiving a health care intervention consider it appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention” [15]. Assessing an intervention's acceptability involves evaluating how well the target population will respond to it and how much of its components suit the needs of the target demographic and organizational setting [14,16,17]. Acceptability studies are important in developing and evaluating complex interventions [18,19]. It helps to reduce the risk of unsuccessful implementation, reduces distrust, improves adherence to the plan, and increases the likelihood of its sustainability [14,16,20–23].

Thus, assessing the acceptability of a PairEd-C intervention is particularly important to make all necessary modifications before evaluating the intervention clinically and understanding how best it can be implemented. The aim of this study is, therefore, to explore the prospective acceptability of PairEd-C intervention among healthcare providers and parents of children with cancer to optimize further development, evaluation, and, ultimately, its implementation.

Method

Study setting and design

The study will be conducted at the pediatric haemato-oncology unit of Tikur Anbessa Specialized

Hospital, Addis Ababa, Ethiopia. This unit is the country's main referral center for child cancer treatment. It provides care by pediatric haemato-oncologists, pediatric haemato-oncology fellows, pediatric residents, oncology nurses, and generic nurses. The unit also has social workers and psychologists. Each year, the unit provides care for about 600 new cases of children with cancer. The child cancer treatment was mainly provided using chemotherapy, radiotherapy, and surgery.

Study design

A descriptive/exploratory qualitative study will be employed to assess the prospective acceptability of the newly designed PairEd-C intervention using the Theoretical Framework of Acceptability (TFA).

Participant Recruitment

Since our objective is to assess acceptability from both parents of children with cancer and the healthcare delivery side, the study participants will be the parents of children with cancer and healthcare providers (physicians, nurses, social workers, and team leaders) working in the unit. In addition, policymakers will be interviewed to get their perspectives on the intervention. Parents of children with cancer who visit pediatric oncology and meet our inclusion criteria will be invited to participate in the in-depth interview. We anticipate recruiting a total of 5 parents of children with cancer. During the selection of parents, maximum variation will be maintained by residence, education status, and type of childhood cancer. Ten healthcare providers (physicians, nurses, and psychologists) were planned to be included in the in-depth interviews. During the selection of health providers, responsibility in the unit, service year at pediatric oncology, working area, and level of education will be considered. Saturation will be regarded to determine the final number of study participants.

Theoretical framework

We have adapted the 'Theoretical Framework of Acceptability (TFA)' developed by Sekhon et al. to guide this study (21). TFA is designed explicitly to assess the acceptability of healthcare interventions from the perspectives of people receiving and delivering interventions. It sets out a theory-informed structure based on participants' cognitive and emotional responses (21). It consists of seven conceptually different constructs that capture essential acceptability dimensions: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy [15]. See Figure 1. It can be applied before, during, or after intervention provision to assess prospective, concurrent, and retrospective acceptability. Since its development in 2017, it has been applied in varied contexts for these purposes [24–27]. It has also been used for structured data analysis [26,28–31], developing questionnaires [32,33], or informing an interview guide development [24,27,34–36]. TFA can be applied using quantitative, qualitative, or mixed study approaches.

For the current study, TFA is suitable since its concepts are applicable for evaluating an intervention in individual, interpersonal, and community contexts. Similarly, the 'PairEd-C' intervention is planned to be delivered for parents of children with cancer coming from different socio-economic backgrounds. As a result, to evaluate it, a framework with components that are applicable for assessing how context-specific demands are met by providing a workable and culturally relevant solution must be used. Therefore, we planned to evaluate acceptability as the perception among beneficiaries and intervention implementers. This aids in determining whether the current intervention will be agreeable, palatable, or satisfactory. This will help to obtain more collective feedback about the nature of the 'PairEd-C' intervention from different stakeholders [15,37]. In addition, assessing anticipated acceptability before participation can highlight which aspects of the intervention could be modified to increase acceptability and, thus, participation [15].

The PairEd-C intervention

The development of PairEd-C intervention was conducted by using the integration of MRC [23] and the Behavior Change Wheel (BCW) [38] models. These theoretical foundations were used for similar designing interventions in different setups. The BCW was developed from frameworks of behavior change and includes the behavior system known as COM-B at the center [38]. The COM-B includes capability (C), opportunity (O), and motivation (M), which ultimately interact to produce behaviors (B) [38]. The behavior of parents that are required to be modified includes their intention to be involved in their childcare, to ask and communicate with health care providers, and to communicate with other parents of children with cancer. The BCW includes nine intervention functions and seven policy categories that support intervention design [38]. The main PairEd-C intervention components will align with the following intervention functions: education, persuasion, training, environmental restructuring, modeling, and enablement. These intervention functions were intended to improve FCC at the pediatric oncology unit through the provision of structured and comprehensive parental education and counseling for parents of children with cancer.

The main intervention components are providing training for the healthcare team, discussion among healthcare providers and setting a shared plan, improving commitment of the healthcare team, providing education for parents, improving parents' capacity to attend, monitoring and utilizing the intervention, arranging discussion among parents of children with cancer and education and counseling on distress. The healthcare providers will receive training on the designed intervention. The trained HCPs will be responsible for implementing the other components, including providing training to parent-peer educators. The trained educators with the health care provider will be involved in providing education for parents, facilitating discussion among parents, improving parenting capacity, and providing education and counseling in stress management. The detailed intervention description is presented using the TIDieR (Template for intervention description and replication) checklist. See Table 1. Figure 2 presents a logic model developed to link the healthcare systems context, such as the study setting, the resources, intervention activities, theory, and assumptions underlying the intervention, and the intervention plan, in a logical order. In addition, Figure 3 is presented to show the flow of the implementation of intervention components for the provision of comprehensive, structured education and counseling for parents of children with cancer. Table 1: The TIDieR (Template for intervention description and replication) checklist (Hoffman et al., 2014)

1. Brief name	Family-centered PairEd-C (Parent education and counseling) intervention for childhood cancer.
2. (Why): Rationale, theory, or goal of the elements essential to the intervention.	<ul style="list-style-type: none"> - To improve FCC at the pediatric oncology unit through the provision of structured and comprehensive parental education and counseling - Improved FCC will improve parents' psychological health conditions. - Systematically developed based on the MRC framework and the behavior change wheel model.
3. (What materials): Describe any physical or informational	- Parents will receive education and counseling on general information about cancer, cancer

<p>materials used in the intervention, including those provided to participants or used in intervention delivery or training intervention providers.</p>	<p>treatment, side effects and management of cancer treatment, providing care for sick child at home and hospital, and coping with a child's diagnosis of cancer.</p> <ul style="list-style-type: none"> - Training manual for parents and health care provides - Parents will receive teaching aids at the end of each session.
<p>4. (What procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.</p>	<ul style="list-style-type: none"> - The intervention will be implemented in four consecutive phases (figure 1). <ul style="list-style-type: none"> • Phase I: preparation of setups in the pediatric oncology unit. • Phase II: providing training for healthcare providers (nurses). • Phase III: providing training for family peer educators. • Phase IV: participant selection and provision of parent education and counseling - Parents will be provided with comprehensive information related to childhood cancer through a series of 12 consecutive sessions. - The group discussion will follow information delivery using face-to-face counseling, videos, leaflets, and cartoon dialogs.
<p>5. (Who provided): For each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given.</p>	<ul style="list-style-type: none"> - All healthcare providers in the pediatric oncology unit will receive training on PairEed-C intervention for childhood cancer. - Nurses with an MSc in oncology will be assigned as coordinators and lead the intervention provision. - Other healthcare providers will help in informing and recruiting parents. - The trained parents will facilitate parent group discussions and help as liaisons between parents

	and HCPs.
6. (How): Describe the modes of delivery (such as face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	<p>The intervention will be delivered using multiple approaches;</p> <ul style="list-style-type: none"> - Face to face <ul style="list-style-type: none"> • individual counseling, • group discussions led by trained parents and - Videos, leaflets, and cartoon dialogs to provide information
7. (Where): Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	<ul style="list-style-type: none"> - The intervention will be conducted at Tikur Anbessa Specialized Hospital (TASH) pediatric oncology unit. - Parents of children visiting inpatient and outpatient units will participate in the intervention.
8. (When and how much): Describe the number of times the intervention was delivered and over what period, including the number of sessions, their schedule, and their duration, intensity, or dose.	<ul style="list-style-type: none"> - The PairEed-C intervention will be delivered every two weeks across 28 weeks. - The overall intervention is classified into 12 sessions. - The parents will receive the intervention when they visit the unit for regular child appointments.
9. (Tailoring): If the intervention was planned to be personalized, titrated, or adapted, describe what, why, when, and how.	<ul style="list-style-type: none"> - The intervention schedule might be modified based on the child's condition and treatment plan. - Parents can also visit the intervention team whenever the need arises. - The topic will be prioritized based on the child's illness, treatment type, and parents' preference. - This will help to address the parents' needs.
10. (Modifications): If the intervention was modified during the course of the study, describe the changes	<ul style="list-style-type: none"> - Not applicable. We are currently in the MRC framework's design phase, and this section cannot be described until the study is complete.
11. (How well [planned]): If intervention adherence or fidelity	<ul style="list-style-type: none"> - Designed and assessed according to the five domains of the National Institute of Health

was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	(NIH) Treatment Fidelity Framework
12. (How well [actual]): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	<ul style="list-style-type: none"> - Not applicable. The intervention is currently in the design phase. - The pilot testing, feasibility, and intervention evaluation will be conducted in the future.

Data collection

Before data collection, a summarized description of the intervention prepared in the local language, Amharic, will be provided for the study participant. The description of the intervention includes the major activities provided in Table 1. In addition, detailed answers will be provided for any questions raised by the study participants. Data will be collected by in-depth interview using a semi-structured interview guide. The interview guide is developed based on seven dimensions of Sekhon's TFA [15] to the designed intervention. See Table 2. We have used recommendations by Sekhon et al. [32] and similar studies to develop the interview guide [24,36,39]. For instance, 'burden' was explored with the question, '*How easy or difficult do you think to participate in the parent education or counseling sessions?*'. The interview guides will be pilot tested after they are independently evaluated by two researchers with experience in public health and complex behavior change interventions. We will use the process of 'back coding' to check whether the interview guide is aligning with TFA constructs. A draft interview guide with opening and closing questions arranged in a random sequence and a list of the TFA structures was sent to the implementation researchers. They were asked to indicate which TFA construct each question addressed and rate how certain they were of this matching (e.g., certainty rating 1–5; 5 = sure, through to 1 = not at all sure). This process was used to assess construct validity and whether the interview guide adequately represented the constructs in the framework [40]. All interviews will be digitally recorded by a portable audio recorder and transcribed verbatim.

Table 2: In-depth interview guide: the interview guide is prepared with TFA definitions to provide guidance for interviewers.

Demographic characteristics	For parents	For healthcare providers
	1. Parent age _____ 2. Child age _____ 3. Family sex _____ F _____ 4. Your relationship with the child _____ 5. Your educational status _____ 6. Residence; Urban/Rural _____ 7. Your child's cancer diagnosis _____ 8. Your child's treatment status _____ 9. Your child's type of treatment (chemotherapy, radiotherapy, both, off treatment, other) _____ 10. Time since your child has been ill ____ 11. Time since your child started treatment	1. Age _____ 2. Sex _____ 3. Profession _____ 4. Service year _____ 5. Your current position _____ 6. Time since assigned in your current position _____

Introduction	<p>For parents of children with cancer</p> <ul style="list-style-type: none"> - Can you talk me through the family-centered care you received at the pediatrics oncology unit? - How do you explain the attention and the care you received as a parent of a child with cancer? <p>Prompts:</p> <p><i>Information you received about your child's illness, cancer treatment, and diagnostic procedure? During your stay in hospital or your child is treated in OPD?</i></p> <p>For healthcare providers and health leaders</p> <ul style="list-style-type: none"> - Can you talk me through your care at the pediatrics oncology unit? - How do you explain the attention and the care you provide for parents of a child with cancer? <p>Prompts:</p> <p><i>What information do you provide about child illness, cancer treatment, and diagnostic procedures? During their stay in hospital or child treatment in OPD?</i></p>	
Affective Attitude: How an individual feels about participating in the intervention	<ul style="list-style-type: none"> - What are your overall feelings towards the planned intervention (your thoughts or feelings)? <p>Prompts:</p> <p><i>For parents of children with new diagnoses? For parents of children with treatment follow-up? For a child on a different treatment regimen (chemotherapy/surgery)? For a parent visiting OPD? Admitted child?</i></p> <ul style="list-style-type: none"> - How comfortable did you feel receiving/providing the designed intervention? 	
Burden: related to self-efficacy and focuses on the perceived amount of effort required to participate in the intervention.	<ul style="list-style-type: none"> - How much effort did it take to participate in the designed intervention? - How easy or difficult do you think to participate in the parent education or counselling sessions? What do you think makes the intervention easy or difficult? <p>Prompt: <i>for parents of children with cancer? For health care providers? For other family members?</i></p>	
Ethicality: The extent to which the intervention has a good fit with an individual's value system	<ul style="list-style-type: none"> - Do you think there are any moral or ethical issues (moral or ethical consequences) related to offering PairEd-C intervention? <p>Prompt: <i>In addressing parents from different socio-demographic backgrounds? Considering inequity in delivering the intervention?</i></p> <ul style="list-style-type: none"> - How do you evaluate cultural appropriateness, including the language of the intervention? 	
Perceived Effectiveness: The extent to which the intervention is perceived to have achieved its intended purpose	<ul style="list-style-type: none"> - Do you think PairEd-C intervention will be effective for the family of children with cancer? What are the possible outcomes of the interventions? <p>Prompt:</p> <p><i>Can we help get a better understanding of child illness, treatment, diagnostics, and treatment procedures? In coping with a child's health condition? Improving overall parental and child health conditions? Improving parents' capacity to provide</i></p>	

	<i>care for their sick child?</i>
Intervention Coherence: The extent to which the participant understands the intervention and how it works	<ul style="list-style-type: none"> - How do you predict the possible clarity (aim (purpose)) of the intervention for parents of children with cancer and/or for health care providers? - How complex will the intervention be for parents of children with cancer and/or for health care providers?
Opportunity Cost: The benefits, profits, or values that would be given up engaging in the intervention	<p>Parents</p> <ul style="list-style-type: none"> - What other priorities can the intervention possibly interfere with? Compared to different activities in the hospital, how much do you think this intervention needs priority? <i>Parents priority? Health care providers' priority?</i> - Was there anything that you/health care providers would possibly give up so that you receive PairEd-C intervention? Prompts: <i>For newly diagnosed? Child on follow-up? Inpatient Vs. outpatient?</i> <p>For healthcare providers</p> <ul style="list-style-type: none"> - What other priorities can the intervention possibly interfere with? <i>Parents priority? Health care providers' priority?</i> - Is there anything that you/parents of children with cancer would possibly give up so that you can provide PairEd-C intervention? Prompts: <i>For newly diagnosed? Child on follow-up? Inpatient Vs outpatient?</i>
Self-efficacy: The participant's confidence that they can perform the behavior (s) required to participate in the intervention	<p>For Parents</p> <ul style="list-style-type: none"> - How confident are you that you will receive and complete the PairEd-C intervention? - How confident are you in using and understanding the education and teaching materials given by PairEd-C intervention? <p>For healthcare providers</p> <ul style="list-style-type: none"> - How confident are you in delivering complete PairEd-C intervention?
Closing	<ul style="list-style-type: none"> - Do you have any comments about the planned intervention? - Is there anything that you think could be done better? - Is there anything else you'd like to tell us? - Any other additional concerns on its acceptability?

Qualitative data Analysis

Qualitative data analysis will use both deductive and inductive qualitative content analyses. Deductive thematic coding was used with a framework analysis technique based on the seven constructs of TFA [15]. In this phase, the text units were condensed, coded, and labeled using the participants' own words as much as possible. Two independent researchers coded all transcripts, resolving discrepancies through consensus or discussion with a third party. During the coding process, quotes will be determined to be generally positive, negative, or neutral toward the designed intervention. Similar codes will be merged into key themes and categorized into domains of the TFA where applicable. Themes that do not fit within the constructs and domains of the TFA will also be listed as new insights that emerged from the interview. In addition, continuous data analysis will be

performed following each in-depth interview. A saturation evaluation will be conducted, and data collection will cease once data saturation is reached during analysis and no new categories are identified. Atlas.ti version 9 will be used for data management. To ensure trustworthiness, we will utilize triangulation, debriefing, and member checking [41]. Triangulation involves cross-verifying data from various sources, including parents, nurses, oncologists, and head nurses.

Ethical consideration

Ethical clearance was obtained from the Addis Ababa University College of Health Science institutional review board with protocol number 022/22/SPH. Permission was obtained from the TASH pediatric oncology unit. Written informed consent for the interviewee will be obtained from each study participant. Participants will be assured of their right to withdraw from the interview at any time, and participation in this study or refusal to participate would not affect their ability to access health services or any other services. Names and other personal information will not be taken or recorded. All information will be kept confidential.

Dissemination

This study's findings will be published in an open-access journal and via national and international conference presentations.

Result

This acceptability study is expected to show that the designed parent education and counseling (PairEd-C) intervention will be acceptable by both healthcare providers and parents of children with cancer. In addition, we expect to obtain an important finding that will be used to improve the intervention before progressing to the next step of our project.

Discussion

This study protocol describes the prospective acceptability of a newly designed intervention to improve FCC in the pediatric oncology setting in Ethiopia. A panel of experts in the field of pediatric oncology will modify the designed intervention based on information obtained from baseline surveys, international experiences, and their expertise. Even though the FCC has great flexibility and can be applied to a multitude of healthcare settings [42], studies on the design and evaluation of FCC intervention in low-income countries were scarce. The intervention protocol for implementing FCC in pediatric oncology settings is lacking in Ethiopia. Acceptability studies for healthcare interventions are becoming more widely recognized as a necessary condition (21), and TFA has been shown to be successful in exploring acceptability in health promotion interventions [28]. Therefore, this prospective acceptability study will establish strong foundational evidence that will play a vital role in the success of the newly developed intervention. In addition, the acceptability study will help to identify factors that would facilitate the acceptability of interventions to improve the designed family-centered education and counseling programs. The findings will also determine the strengths and weaknesses of the proposed intervention. We will also benefit from aligning the intervention with the existing child cancer treatment.

Strengths and Limitations

The strength of the current study is that it used a widely used framework to guide the study. Having an intervention developed based on locally generated information and experts who understand the available setup will facilitate the acceptability of the intervention. Involving health service leaders, health care providers, social workers, and parents of children with cancer will help to obtain more comprehensive information about the possible acceptability of the designed intervention. Regarding

possible limitations of the study, parents' feedback might be biased due to their anticipation of trying something new. Social desirability bias might be introduced because of the nature of the study's interview. In addition, the transferability of the findings might be limited due to the purposive nature of participant selection.

Conclusion

The result of the acceptability study will indicate that the designed intervention will be well received and accepted. The feedback obtained from parents, HCPs, and policymakers will be positive in all domains of TFA. The education and counseling methods designed in the proposed intervention will significantly improve parent understanding of their child's illness and enhance their capacity to provide care. It will also help to fulfill the information needs of parents of children with cancer. In addition, we expect study participants will respond as the intervention will help to reduce parental psychological distress that is caused by their child's diagnosis of cancer. Components of the proposed intervention, such as its detailed nature, HCPs, peer educators training, delivery of information using multiple methods, and delivery of the intervention in integration with regular care, will help make it more acceptable among parents and HCPs. The outcome of this study will also help to identify possible challenges that might affect the implementation of the study. Furthermore, the findings will help to identify potential areas of improvement.

Abbreviations

BCW - Behavior Change Wheel; FCC-Family-centered care, HCPs - Healthcare providers; MRC-Medical Research Council; PairEd-C - parent education and counseling; TASH - Tikur Anbessa Specialized Hospital; TFA- theoretical framework of acceptability.

Data Availability

Data sharing does not apply to this protocol, as no data sets have been collected or analyzed.

Conflicts of Interest

None declared.

Authors contribution

Leul Deribe (LD), Adamu Addissie (AA), Eshetu Girma (EG), Abdulkadir Gidey (AG), Solomon Teferra (ST), and Nataliya Berbyuk Lindström (NBL) conceived, designed, implemented, conducted data analysis, supervised, reviewed, corrected manuscript draft and interpreted the study results. All authors have read and approved the final manuscript.

Funding

This work was supported by the Swedish Research Council (Vetenskapsrådet; grant number: 2017-05410, <https://www.vr.se/>)

Acknowledgments

The authors acknowledge all study participants for generously providing information and exhibiting patience during interviews. Furthermore, our deepest gratitude is extended to the experts involved in preparing this intervention. We would also like to acknowledge the staff of the pediatric oncology unit for their assistance during data collection and designing interventions.

Disclosure of generative AI use

“The author(s) attest that there was no use of generative artificial intelligence (AI) technology in the generation of text, figures, or other informational content of this manuscript.”

Reference

1. Carrie, AK K, Hill SJ. Family-Centered Care from the Perspective of Parents of Children Cared for in a PICU: An Integrative Review. *Physiol Behav.* 2019;176: 139–148.
2. Shields L, Pratt J, Davis L, Hunter J. Family-centred care for children in hospital. In: Shields L, editor. *Cochrane Database of Systematic Reviews*. Chichester, UK: John Wiley & Sons, Ltd; 2007. doi:10.1002/14651858.CD004811.pub2
3. Okunola I, Olaogun AA, Adereti SC, Bankole A, Oyibocha E, Ajao O. Peadiatric Parents and Nurses Perception of Family-Centered Nursing Care in Southwest Nigeria. *Int J Caring Sci.* 2017;10: 67–75. Available: www.internationaljournalofcaringsciences.org
4. Abdel Razeq NM, Arabiat DH, Shields L, Razeq NMA, Arabiat DH, Shields L, et al. Nurses' Perceptions and Attitudes toward Family-Centered Care in Acute Pediatric Care Settings in Jordan. *J Pediatr Nurs.* 2021;61: 207–212. doi:10.1016/j.pedn.2021.05.018
5. Prasopkittikun T, Srichantarant A, Chunyasong S. Thai nurses' perceptions and practices of family-centered care: The implementation gap. *Int J Nurs Sci.* 2020;7: 74–80. doi:10.1016/j.ijnss.2019.09.013
6. Done et al. Pediatric Nurses' Perspectives on Family-Centered Care in Sri Lanka : *Child Heal Nurs Res.* 2020;26: 72–81.
7. Bruce B, Letourneau N, Ritchie J, Larocque S, Dennis C, Elliott MR. A multisite study of health professionals' perceptions and practices of family-centered care. *J Fam Nurs.* 2002;8: 408–429. doi:10.1177/107484002237515
8. Coyne I, Murphy M, Costello T, O'Neill C, Donnellan C. A Survey of Nurses' Practices and Perceptions of Family-Centered Care in Ireland. *J Fam Nurs.* 2013;19: 469–488. doi:10.1177/1074840713508224
9. Emmamally W, Brysiewicz P. Family-centred practices of healthcare professionals in three emergency departments in KwaZulu-Natal, South Africa. *South African J Crit Care.* 2018;34: 38–43. doi:10.7196/SAJCC.201.v34i2.358
10. Lim SJ, Bang KS. The perceptions and performance of family-centered care among pediatric nurses at a children's hospital in South Korea: a descriptive study. *Child Heal Nurs Res.* 2023;29: 207–217. doi:10.4094/chnr.2023.29.3.207
11. Ekberg K, Schuetz S, Timmer B, Hickson L. Identifying barriers and facilitators to implementing family-centred care in adult audiology practices: a COM-B interview study exploring staff perspectives. *Int J Audiol.* 2020;59: 464–474. doi:10.1080/14992027.2020.1745305
12. Phiri PGMC, Chan CWH, Wong CL. The scope of family-centred care practices , and the facilitators and barriers to implementation of family-centred care for hospitalised children and their families in developing countries : An integrative review. *J Pediatr Nurs.* 2020;55: 10–28. doi:10.1016/j.pedn.2020.05.018
13. Zandoni P, Scime N V., Benzies K, McNeil DA, Mrklas K. Facilitators and barriers to implementation of Alberta family integrated care (FICare) in level II neonatal intensive care units: A qualitative process evaluation substudy of a multicentre cluster-randomised controlled trial using the consolidated framework. *BMJ Open.* 2021;11. doi:10.1136/bmjopen-2021-054938
14. Ayala GX, Elder JP. Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. *J Public Health Dent.* 2011;71: 1–17. doi:10.1111/j.1752-7325.2011.00241.x

15. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Serv Res.* 2017;17: 1–13. doi:10.1186/s12913-017-2031-8
16. BERNAL G. Intervention Development and Cultural Adaptation Research With Diverse Families. *Fam Process.* 2006;45: 143–151. doi:10.1111/j.1545-5300.2006.00087.x
17. L. Kay Bartholomew Eldredge, Christine M. Markham, Robert A. C. Ruiter, María E. Fernández, Gerjo Kok GSP. Planning Health Promotion Programs: An Intervention Mapping Approach. 2016. הארץ.
18. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new Medical Research Council guidance. *Bmj.* 2008;337: 979–983. doi:10.1136/bmj.a1655
19. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350: 1–7. doi:10.1136/bmj.h1258
20. Prestwich A, Kenworthy J, Conner M. Health Behavior Change: Theories, Methods and Interventions. *Health Behavior Change: Theories, Methods And Interventions.* 2017. doi:10.4324/9781315527215
21. Garizábalo-Dávila CM, Rodríguez-Acelas AL, Cañon-Montañez W. Usefulness of Acceptability and Feasibility Assessment in Studies of Nursing Interventions. *Investig y Educ en Enferm.* 2023;41: 11–14. doi:10.17533/udea.iee.v41n1e02
22. Klaic M, Kapp S, Hudson P, Chapman W, Denehy L, Story D, et al. Implementability of healthcare interventions: an overview of reviews and development of a conceptual framework. *Implement Sci.* 2022;17: 1–20. doi:10.1186/s13012-021-01171-7
23. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. *BMJ.* 2021;374: 1–11. doi:10.1136/bmj.n2061
24. Pavlova N, Teychenne M, Olander EK. The concurrent acceptability of a postnatal walking group: A qualitative study using the theoretical framework of acceptability. *Int J Environ Res Public Health.* 2020;17: 1–9. doi:10.3390/ijerph17145027
25. Scott SE, Rauf B, Waller J. “Whilst you are here...” acceptability of providing advice about screening and early detection of other cancers as part of the breast cancer screening programme. *Heal Expect.* 2021;24: 1868–1878. doi:10.1111/hex.13330
26. Toomey E, Flannery C, Matvienko-Sikar K, Olander EK, Hayes C, Heffernan T, et al. Exploring healthcare professionals’ views of the acceptability of delivering interventions to promote healthy infant feeding practices within primary care: A qualitative interview study. *Public Health Nutr.* 2021;24: 2889–2899. doi:10.1017/S1368980020004954
27. Groarke JM, Richmond J, Mc Sharry J, Groarke AM, Harney OM, Kelly MG, et al. Acceptability of a mobile health behavior change intervention for cancer survivors with obesity or overweight: Nested mixed methods study within a randomized controlled trial. *JMIR mHealth uHealth.* 2021;9: 1–12. doi:10.2196/18288
28. Murphy AL, Gardner DM. Pharmacists’ acceptability of a men’s mental health promotion program using the Theoretical Framework of Acceptability. *AIMS Public Heal.* 2019;6: 195–208. doi:10.3934/publichealth.2019.2.195
29. Putri LP, Mawarni D, Trisnantoro L. Challenges of Shifting Diabetes Mellitus Care From Secondary- to Primary-Level Care in Urban and Rural Districts: A Qualitative Inquiry Among Health Providers. *J Prim Care Community Heal.* 2020;11. doi:10.1177/2150132720924214
30. Rushton K, Ardern K, Hopkin E, Welsh C, Gellatly J, Faija C, et al. “I didn’t know what to expect”: Exploring patient perspectives to identify targets for change to improve telephone-delivered psychological interventions. *BMC Psychiatry.* 2020;20: 1–13. doi:10.1186/s12888-020-02564-6

31. Sekhon M, Cartwright M, Lawes-Wickwar S, McBain H, Ezra D, Newman S, et al. Does prospective acceptability of an intervention influence refusal to participate in a randomised controlled trial? An interview study. *Contemp Clin Trials Commun.* 2021;21: 100698. doi:10.1016/j.conctc.2021.100698
32. Sekhon M, Cartwright M, Francis JJ. Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions. *BMC Health Serv Res.* 2022;22: 1–12. doi:10.1186/s12913-022-07577-3
33. Aboaja A, Atewogboye O, Arslan M, Parry-Newton L, Wilson L. A feasibility evaluation of Discovery Group: determining the acceptability and potential outcomes of a patient-led research group in a secure mental health inpatient setting. *Res Involv Engagem.* 2021;7: 1–10. doi:10.1186/s40900-021-00310-0
34. Ferdiana A, Cintyamina U, Azizatunnisa' L, Sunandar E, Probandari A. Finding the right balance: implementation of public–private partnership in artemisinin-based combination therapy provision in Manokwari, Indonesia. *J Pharm Policy Pract.* 2021;14: 1–12. doi:10.1186/s40545-021-00347-2
35. Ngowi K, Pima F, Mmbaga BT, Aarnoutse RE, Reiss P, Nieuwkerk PT, et al. “I Wish to Continue Receiving the Reminder Short Messaging Service”: A Mixed Methods Study on the Acceptability of Digital Adherence Tools Among Adults Living with HIV on Antiretroviral Treatment in Tanzania. *Patient Prefer Adherence.* 2021;15: 559–568. doi:10.2147/PPA.S290079
36. Paynter C, McDonald C, Story D, Francis JJ. Application of the theoretical framework of acceptability in a surgical setting: Theoretical and methodological insights. *Br J Health Psychol.* 2023; 1153–1168. doi:10.1111/bjhp.12677
37. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Heal Ment Heal Serv Res.* 2011;38: 65–76. doi:10.1007/s10488-010-0319-7
38. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. The Behavior Change Wheel: Book Launch Event. 2014.
39. Timm L, Annerstedt KS, Ahlgren JÁ, Absetz P, Alvesson HM, Forsberg BC, et al. Application of the Theoretical Framework of Acceptability to assess a telephone-facilitated health coaching intervention for the prevention and management of type 2 diabetes. *PLoS One.* 2022;17: 1–15. doi:10.1371/journal.pone.0275576
40. O’Leary-Kelly SW, Vokurka RJ. The empirical assessment of construct validity. *J Oper Manag.* 1998;16: 387–405. doi:10.1016/s0272-6963(98)00020-5
41. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. *Educ Inf.* 2004;22: 63–75. doi:10.3233/EFI-2004-22201
42. Smith W. Concept Analysis of Family-Centered Care of Hospitalized Pediatric Patients ☆. *J Pediatr Nurs.* 2018;42: 57–64. doi:10.1016/j.pedn.2018.06.014

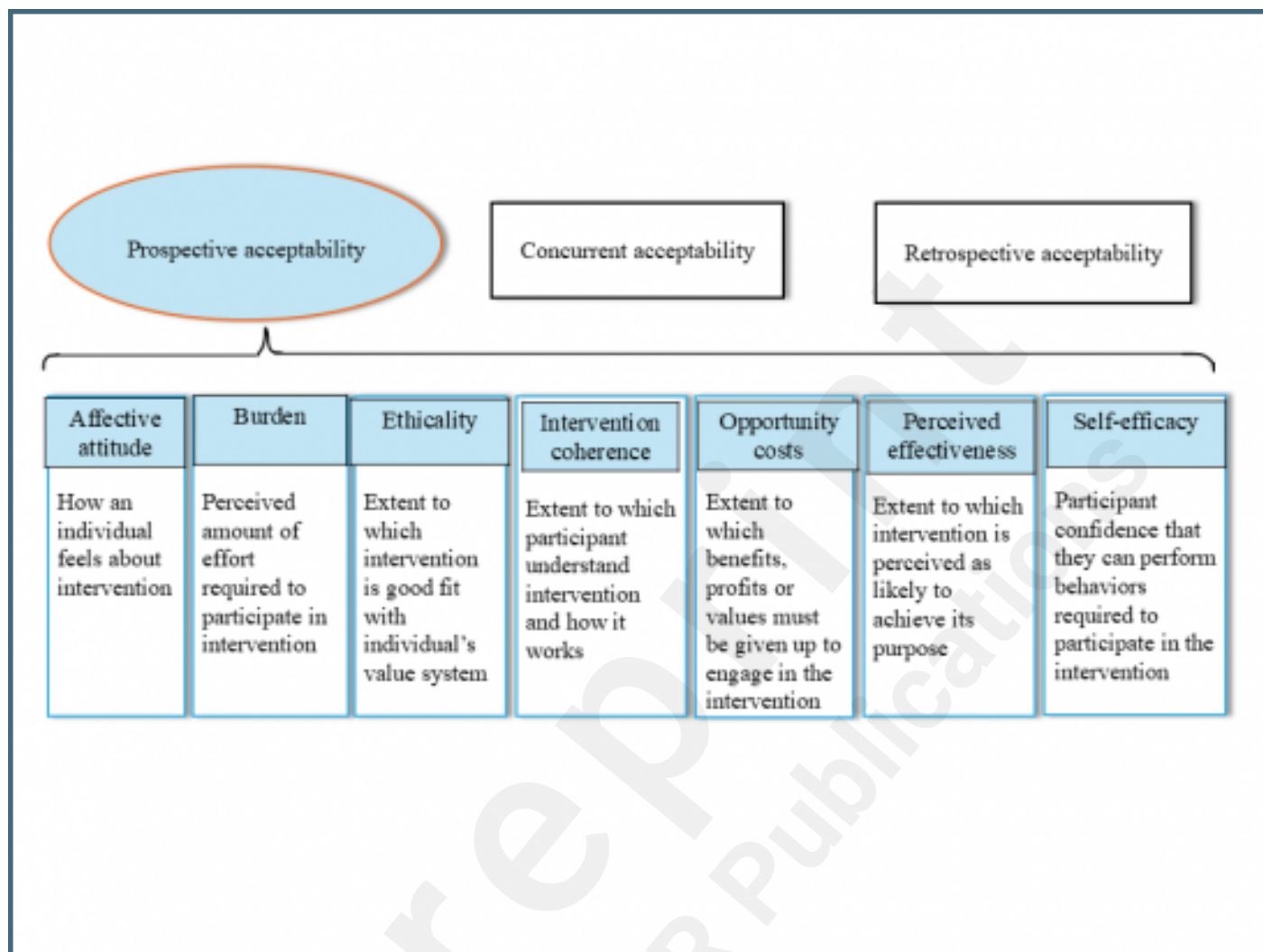
Supplementary Files

Untitled.

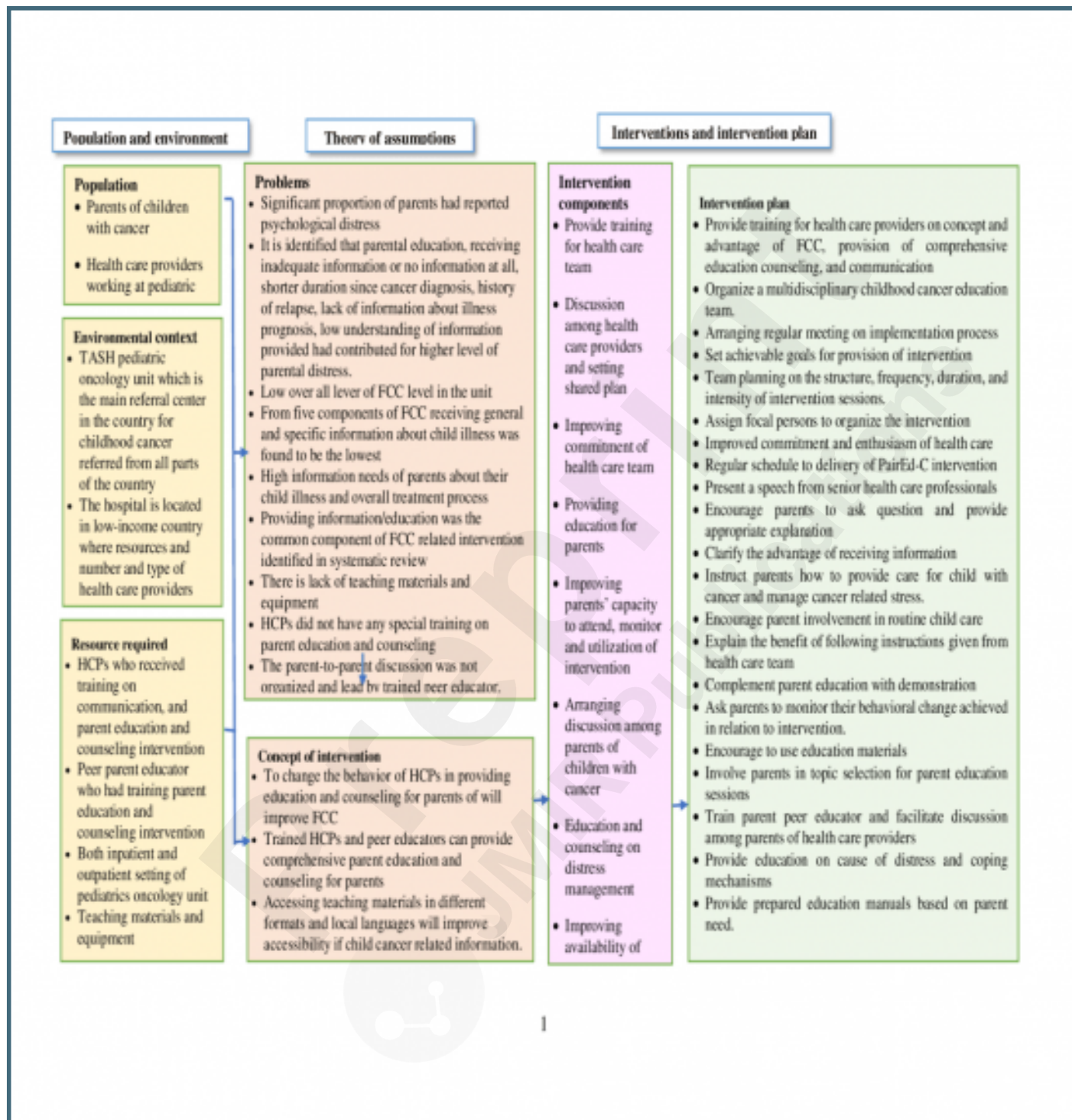
URL: <http://asset.jmir.pub/assets/90501cc47343ede72a306104ae8921f1.docx>

Figures

Theoretical framework of acceptability developed by Sekhon and colleagues [15].



Logic Model linking context of the healthcare system, resources, and intervention activities (Conrad et al., 1999).



Flow chart for the implementation of intervention components for provision of comprehensive structured education and counselling for parents of children with cancer.

