

# 1. Evaluation of an interdisciplinary intervention for children with multiple referrals to specialist healthcare.

## 2. Introduction

WHO names fragmented care as one of five major challenges of present day healthcare [1]. This is particularly true for patients with complex and unexplained health complaints. These children often have multiple referrals to both somatic and mental health departments in specialist healthcare. The disconnection of mental healthcare from the rest of healthcare services is seen as one of the greatest shortcomings of the present healthcare system [2]. Researchers estimate that 4-10 % of children and youths in the general population are affected by unexplained health complaints, to such a degree that they need clinical intervention [3]. Unexplained health complaints accounts for almost 50% of children (7-12 years) referred to pediatric clinics, and more than 50% of consultations in pediatric gastroenterology [3]. Every year specialist healthcare, both nationally and internationally, spend considerable healthcare resources on suboptimal care for these children. A fragmented understanding of the individual patient increases the risk of unnecessary examinations, ineffective interventions and costly healthcare utilization [3]. This is unfortunate, as we know that early diagnosis and treatment improve prognosis, and prevents a lengthy and disabling course of illness. Impaired functioning such as reduced participation in leisure activities and school attendance is a major concern. Multiple recurrent health complaints have also been linked to poor quality of life in several studies [4], and risk of reduced physical and psychological health in adulthood [5]. Several studies recommend multimodal, individually adjusted treatment for complex and unexplained health complaints [6,7]. However, few such clinical interventions are developed for children, and none of the developed interventions are systematically evaluated in terms of patient outcomes. Development of sound intervention programs, according to evidence based recommendations, will benefit the patients, their families, the quality and organization of the healthcare services, and also the economic burden for the society.

### **“Tjenester på Tvers” - an interdisciplinary intervention for children with complex and unexplained health complaints and multiple referrals to specialist healthcare**

Haukeland University Hospital (HUH) have seized the opportunity to improve healthcare for children with complex and unexplained health complaints and multiple referrals to HUH, and developed an interdisciplinary intervention for these children. This intervention originated from several years of clinical experience and feedback from families and children with complex somatic and mental health complaints and multiple referrals to HUH. The development of the intervention is also informed by a review of relevant literature, our own prestudies at HUH, and user involvement in planning and developing the intervention. In “Tjenester på Tvers” we offer a coordinated, interdisciplinary and individually tailored intervention for children with multiple referrals to specialist healthcare. We believe that this will increase quality of life, school attendance and social participation, and reduce healthcare costs for our target group.

The intervention program has been developed in several steps [8-10], and has been running since 2016. The aim of the current project is to evaluate the effect of this intervention as defined by patient/ family satisfaction as well as by changes in quality of life and the level of functioning (school attendance). A randomized controlled trial started in 2021, where TpT-intervention is compared to treatment as usual. The TpT-intervention is based on a biopsychosocial and systemic model for children with complex and unexplained health complaints and their families, and inspired by Kozłowska's stress-system approach to assessment and treatment [11]. This model aims to connect body, mind, and social environment in understanding the child's symptoms [11]. In the TpT-consultation, factors maintaining the child's symptoms are explored as well as the child's present and previous history of stress. Further, the child's ability to self-regulate is addressed to promote health and functioning in his/her family. Given the heterogeneous nature of this patient group, the

assessment is personalized to the individual child, adjusted to meet the needs of each child and family, in line with Kozłowska's framework [11].

Time	Patient and family	Professional team
30 min pre-intervention	Meet the research nurse and fill out the questionnaires	Prepare for the intervention
15-30 min	Patient and family share their concerns and health complaints to the joint team	
15 min		Planning of the intervention/customizing program for patient
45-60 min	Intervention/ Diagnostic assessment/Clinical examination	
15 min		Reflection on findings from the assessment
45 min	Summarizing the day as a joint team including agreement on further treatment plans.	

For the scientific evaluation of the TpT-intervention there are four different TpT-teams; two focusing on neurology and two focusing on gastroenterology. Each TpT- team consists of a paediatrician, a physiotherapist and a psychologist. To ensure team compliance with the procedure we will regularly make video recording evaluating and give feedback to the four teams. Prior to the TpT-intervention, the child and its parents/guardians fill out questionnaires about health status and previous experiences with health care services, while the TpT-team prepares the consultation (Table 1). The intervention focus on a collaborative approach to the families, culminating in a joint summary of the day together with the child and family, agreeing on further interventions. This summary includes the family in making a shared decision on how to understand the child's symptoms and disability, assessing if further examinations are necessary, and establishing a treatment plan [12].

**Table 1.** Structured schedule for the intervention

## Originality

This is the first study of effects of an intervention for children with multiple referrals to specialist healthcare including both somatic and mental health services. To our knowledge, this has not been done neither nationally nor internationally. The aim of the TpT-intervention is to reach a common integrative understanding of the *individual* child. This is important because two children with a rather similar symptoms – e.g. long lasting, disabling abdominal pain combined with fatigue and anxiety – may need quite different treatments. An integrative understanding will give insight into the child's needs – both at the individual and the systems level, and contribute to making more targeted treatment measures. In delivering the intervention, focusing on actively involving and collaborating with the family in completing the assessment can become therapeutic in itself [12] and reduce healthcare expenditures considerably [13]. The idea is that through this interdisciplinary intervention the afflicted families and the professionals form a joint team, aiming to make complementary and meaningful assessments and following treatment measures. This collaborative and complementary focus permits us to standardize the structure of the consultation, and to a certain degree its content, but the need for tailored and targeted treatment limits the ability to standardize recommended treatment measures. The teams have been coached, and a PhD candidate from the Norwegian School of Economics (NHH) [16] have closely studied the team adaptation and development. This intervention aims to offer a group of children with multiple referrals a treatment option, not previously available.

### 2.1. Expected impact on patient care

We expect to contribute to establishing and implementing evidence-based interventions for children with multiple referrals and complex unexplained health complaints, both nationally and internationally. We expect that early identification of these patients' needs, and re-organising care processes in interdisciplinary teams, will produce better outcomes for patients and contribute to a more "seamless" clinical pathway. We also expect that the TpT-intervention will increase healthcare

efficiency by reducing the number of unnecessary consultations – and thereby reducing care duplication and healthcare costs, as well as being useful for other patient groups with multiple health complaints, offering possible solutions to this growing challenge. Experiences from piloting this interdisciplinary, integrative TpT-intervention, so far, is that using several hours in the TpT-team, compared to several consecutive single consultations seems to produce better understanding, better outcomes, be more efficient, and especially achieve more satisfaction among the patients and their parents.

### 3. Objectives and goals/Milestones of the project

This PhD project is a part of the main project “*Transitioning Young Patients` Health Care Trajectories`*” described in four parts in Figure 1.

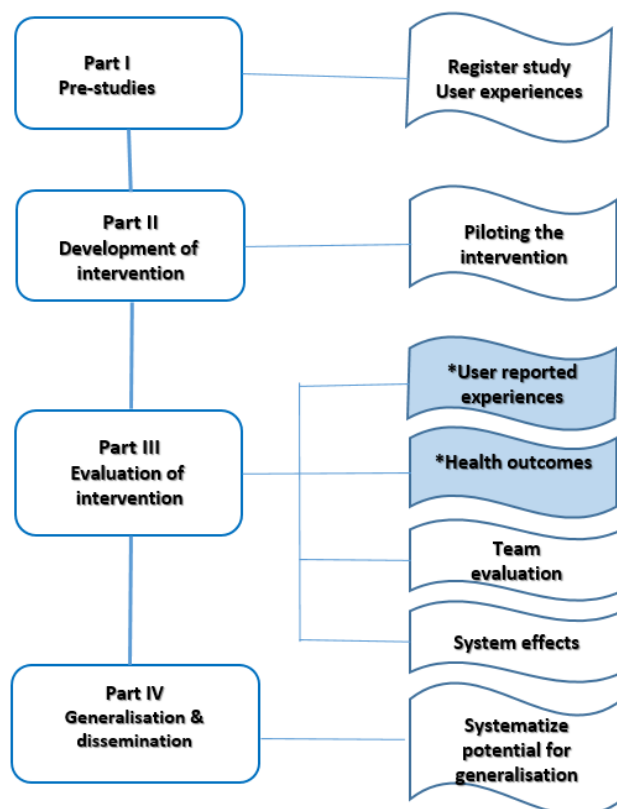
#### Objective

The primary objective of this PhD project is to evaluate a new structured, interdisciplinary intervention (TpT-intervention) for children with multiple referrals to specialist healthcare due to complex and unexplained health complaints. Scholars activities marked with \* in Figure 1.

#### Research questions:

Compared to treatment as usual:

1. How do children with multiple referrals and their parents experience the TpT-intervention?
2. Does the TpT-intervention improve quality of life in children with multiple referrals?
3. Does the TpT-intervention increase functional level in children with multiple referrals?



#### Short term goals

1. Complete a randomized controlled trial of the TpT-intervention for children with multiple referrals to specialist healthcare, measuring possible effects of the intervention on:
  - a. Child and parent experiences with healthcare.
  - b. Quality of life
  - c. Functional level (school attendance)

#### Long term goals

1. Implement effective interdisciplinary interventions for children with multiple referrals to specialist healthcare as standard care at HUH.
  2. Implement effective interdisciplinary interventions for children with multiple referrals and complex health complaints as standard care in all health trusts in Western Norway.
- Through the implementation of the TpT-intervention:
3. Improve prognosis for children with multiple referrals to specialist healthcare.
  4. Prevent chronification of health complaints in children with multiple referrals to specialist healthcare.
  5. Reduce socioethical costs associated with complex health complaints in children.

**Figure 1.** Organization of the main project “*Transitioning Young Patients` Health Care Trajectories`*”.

## Expected results during project period

1. Evaluate the interdisciplinary TpT-intervention through a RCT, in terms of possible effects on child and parent experiences with healthcare, quality of life and school attendance.
  2. Include users as co-researchers through the process to improve and better adjust the intervention to the target group, and to aid in disseminating the results and implementing the intervention.
- The scholars activities in the project is, in collaboration with the involved research environment, to reach the short term goals for the project, through managing the process for evaluating the intervention, gather, process and analyse results (health outcomes) from the RCT, and as first author write the manuscripts for the articles in the proposed thesis.

## Expected impact on knowledge in the research field

Our preliminary results with increased health outcomes have been welcomed by health authorities [15]. However, the effects of such interventions for these children still need scientifically evaluation. The project will thus give valuable knowledge on the use and effect of interdisciplinary interventions for children with multiple referrals due to complex and unexplained health complaints. This could accelerate the development of sound and evidence-based interventions, both nationally and internationally. The lessons learned from this project may impact both national hospital and regional policies, and spread lessons learned to other hospitals and patient groups. Dissemination of findings through our research environment will contribute to strengthening competence in interventions for children with multiple referrals across different departments at the hospital, different service levels, research fields, health trusts and countries.

## 4. Feasibility

### 4.1. Study Design, Choice of Methodology and Analysis

As described in figure 1 this project is at point of part III and the main focus in “*Transitioning Young Patients` Health Care Trajectories*”.

### Part III. A randomized controlled trial of the TpT-intervention for children with complex and unexplained health complaints and multiple referrals to specialist healthcare.

Evaluation of the interdisciplinary intervention by aiming to answer the following research questions:

1. *How do children with multiple referrals and their parents experience the TpT- intervention compared to treatment as usual?*
2. *Does the TpT- intervention improve quality of life in children with multiple referrals?*
3. *Does the TpT- intervention increase functional level in children with multiple referrals?*

**Population:** To enroll patients in the study, every other week a research nurse extracts reports from the hospital record system for the children offered consultations at gastro- or neuro-section at the pediatric department at HUH. The research nurse then contacts the parents/guardians of all eligible (based on inclusion/exclusion criteria) patients by telephone, inviting them to participate in the study. Based on oral consent, written information is sent to the family. At the consultation, written consent is obtained.

**Inclusion/exclusion:** To identify children aged 6-12 years with multiple referrals due to complex and unexplained somatic and mental health complaints at our hospital, we have used the following criteria for inclusion to our study, based on our pre-studies (Part I) [8-10]:

- Three or more new referrals in the last 3 years
- More than 3 different diagnoses in their hospital records including symptoms from neurology or gastroenterology.
- Referred to both somatic and mental health departments during their patient history.

Patients were then excluded if:

- The current referral was classified as an emergency
- The current referral was related to specific diagnoses (e.g. epilepsy or Crohn`s disease).

- The child was in need of the regular scheduled consultation at the Department of Pediatrics.

**Randomization:** Children included in the study will, after signing an informed consent, be randomised independently through sealed envelopes to either the TpT-team intervention or the usual medical care process (controls).

**Control group:** The control group will be offered a pediatric outpatient consultation by either a child gastroenterologist or child neurologist.

**Drop-out:** The patient and the family can withdraw at any time from the study and from the consultation, and return to the original appointment at the pediatric gastro- or neuro-section. In a feasibility study of the intervention completed in 2019, the drop-out rate was 2 out of 32 participants (6%). Attrition is accounted for in power analysis.

**Sample:** For 150 children, they will after signing an informed consent be randomised to either the TpT-intervention or the usual care process (controls) meeting one paediatrician in an outpatient clinic. In 2021-2022 we expect 75 cases and 75 controls to participate in the RCT.

**Method:** The intervention is described in the introduction section under the heading "Tjenester på Tvers". Outcome will be measured as change in Quality of life (QoL) and level of functioning, measured as school attendance, and compared to the control group.

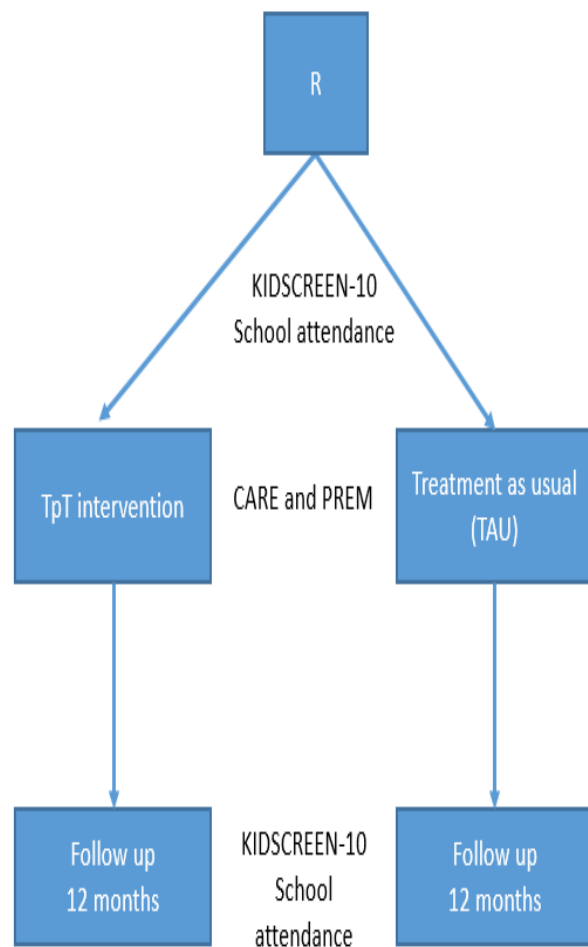
### Measures:

**CARE:** Each child's experience with the TpT-team, will be covered in The consultations and relational empathy (CARE) measure [16], completed by both the control and intervention group right after their first consultation.

**Parent reported experience measure (PREM):** A questionnaire consisting of 5 items covering parent's experience meeting the interdisciplinary team is distributed to parents both directly before and after they participate in the intervention. From the pre-study we have developed a questionnaire regarding parents' previous experiences [9]. As the concordance between child and parent reported experiences are unsure, we need to properly evaluate both in the intervention [17].

**KIDSCREEN-10:** Quality of life (QoL) measured with KIDSCREEN-10 [18] before the intervention and 12 months after.

**School attendance measure:** School absenteeism is measured before the intervention and 12 months after with a five point Likert scale from less than one time in a month, one time a month, one time a week, two days a week, or more than twice a week.



**Figure 2.** Components in PhD workpackage in the randomised controlled trial (RCT).

### **Analysis:**

**CARE and Parent reported experience measures (PREM):** Descriptive analyses will be used to describe the sample (mean, standard deviation, frequency) with SPSS version 26. The intervention group of children will be compared with control group of children by mean score of the different items in CARE and parent reported experience measure. Regression analyses will be performed for adjustments for covariates. We have collected socio-economic data and relevant medical data that will be included in the regression analyses for adjustments for the outcomes.

**KIDSCREEN-10:** Descriptive analyses will be used to describe the sample (mean, standard deviation, frequency) with SPSS. Changes over time for continuous outcomes will be analyzed with mixed models to account for drop-out and missing values. We report estimates with 95% CIs and exact two-sided p-values. We will obtain T-scores; were a mean ( $\pm$  SD) scores of  $50 \pm 10$  define average values for children and adolescents aged 8-18 years across Europe. Group differences in KIDSCREEN-10 can be judged according to the following standard criteria interpretation: trivial ( $< 0.2$  ES), small (0.2–0.5 ES), moderate (0.5–0.8 ES) and large ( $> 0.8$  ES). The intervention group of children will be compared with control group of children by mean scores. This intervention represents a new approach, making it difficult to provide secure estimates of statistical strength and the size of the range we will need. The TpT study is a randomized controlled trial, with random allocation to the TpT intervention or usual care at a 1:1 ratio. The study is designed to detect an effect size (Cohen's d) of 0.50 between the intervention and control group for the primary outcome: QoL measured with the KIDSCREEN-10 questionnaire. Sample size calculations were performed using standard formulas, given  $\alpha = 0.05$ ,  $\beta = 0.8$ , group ratio 1:1, leading to  $n = 64$  children in each group. To account for attrition we will include 75 children in each group.

**School attendance:** A Monte Carlo simulation study was used to estimate the power of a model analyzing school absenteeism in the two groups (75 person in each group,  $N = 150$ ). We assumed a mean increase in the TAU and treatment groups to be 0.2 and -0.1, respectively. With baseline  $SD = 1$  this reflect effect sizes. Residual variances in the measurements over time were set to 0.1, and the linear slope factor set to zero, giving a random intercept fixed slope model. Attrition was set to max 20% ( $y_1: 0; y_2: 0.10; y_3: 0.20$ ). The statistical power of mean changes were found to be 100% (TAU) and 95% (Treatment group). The group difference showed 100% power.

## **4.2 Organization and Collaboration**

### **4.2.1 Project organization, expertise of research community and collaborations**

Our research community includes considerable competence in research on user involvement, user based measures, outcome measures, psychosomatic disorders in children, team evaluation and statistics (Figure 3). The PhD candidate is currently the local Bergen municipality project manager aiming to implement better patient trajectories and collaboration between specialist healthcare, primary healthcare and municipal services for children with signs of mental disorders, through the Helse Vest project, "[Barn og unges helsetjeneste](#)". She is also an experienced clinician in child and adolescent mental health, and has already published scientific articles both nationally and internationally.

Resources	Research environment	Competence profile	Role(s) in the project
Irene Elgen	Research director at the <a href="#">Department of Child and Adolescent Mental Health</a> at HUH/ <a href="#">Department of Clinical Medicine</a> , University of Bergen	Professor, psychiatrist and dr med. Experienced clinician within both pediatric and mental health	Main supervisor Leader of the TpT intervention Member of core research group
Tone Norekvål	<a href="#">Department of Clinical Science/Centre on patient reported outcomes</a>	Professor and RN Expertise in user based measures	Participating in evaluation and supervision regarding PREM part III
John Roger Andersen	<a href="#">Western Norway University of Applied Sciences/Førde Health Trust</a>	Professor and RN. Expertise in user based measures	Participating in evaluation and supervision regarding PROM part III
Rolf Gjestad	<a href="#">Centre for Crisis Psychology, UiB/Department of Research and Development</a> , HUH	Associate professor, PhD. Expertise in Applied statistics	Statistics and analytical modelling part I, II and III.
Helene Helgeland	<a href="#">Department of Child and Adolescent Mental Health in Hospitals</a> , Oslo University Hospital	PhD & child and adolescent psychiatrist. Leader of the <a href="#">National Advisory Unit on Psychosomatic Disorders in Children and Adolescents</a> .	Co-supervisor for the candidate
Gottfried Greve	<a href="#">Department of Heart Disease and Children's Vitality Centre</a> at HUH/ <a href="#">Dpt. of Clinical Science</a> at UiB.	Professor, dr med, paediatrist. Experienced clinician within pediatric health.	Supervisor Member of core research group.
Torhild Heggstad	<a href="#">Department of Research and Development</a> , HUH	PhD and MD. Expertise in health services research	Member of core research group.
Thomas Mildestvedt	<a href="#">Institute of Global Public Health and Primary Care</a> , University of Bergen	Assistant professor and experienced clinician in primary care	Member of core research group. Contributor in primary care link.
Vidar Schei	<a href="#">Norwegian School of Economics (NHH)</a>	Professor and dr oecon. Expertise in team evaluation	Team evaluation part III
Elisabeth Andvik	<a href="#">Norwegian School of Economics (NHH)</a>	PhD student. Team evaluation	Team evaluation part III
Stewart Mercer	<a href="#">Usher Institute, University of Edinburgh</a>	Professor of Primary Care and Multimorbidity. Health services researcher.	Participating in evaluation and writing article 3
Ragnhild Lygre	PhD – candidate	Clinical child psychologist	PhD part I - II - III
Barbro Sulebakk	User representative	User involvement/ user perspectives	Participating in development of the intervention Part I-II-III-IV

**Table 3.** Research environment.

### 4.3 Budget

Details of the budget are entered in the electronic application form.

### 4.4. Plan for Milestones and Dissemination

	2021				2022				2023				2024				2025			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
<b>Evaluation of the intervention</b>																				
<b>Research question 1: Child and parent reported experience</b>																				
Datacollection at T0	→																			
Evaluation - writing paper					→															
<b>Research question 2: Quality of life</b>																				
Datacollection at T12	→																			
Evaluation - writing paper									→											
<b>Research question 3: School attendance</b>																				
Datacollection at T12	→																			
Evaluation - writing paper													→							
<b>Thesis summary</b>																	→			

**Table 4.** Plan for Milestones

We plan for at least three articles as part of this PhD-thesis and with the PhD applicant as first author:

1. *Parent and child experiences with a new interdisciplinary intervention for children with multiple referrals to specialist healthcare.*
2. *Quality of life following a new intervention for children with multiple referrals to specialist healthcare.*
3. *School attendance following a new intervention for children with multiple referrals to specialist healthcare.*

We aim to publish in open access journals in medicine and psychology with high impact. The results of this research will also be disseminated through the National Advisory Unit on Complex Psychosomatic Disorders in Children and Adolescents. We will also propose a collaboration with the National alliance for health psychology in somatic healthcare, the Norwegian paediatric society and the Norwegian child and adolescent psychiatric society to aid the dissemination of the project results. We aim to present our findings in international academic conferences, and take initiative to carry out national symposiums on the subject of compound health complaints and interdisciplinary interventions. The subject has already been addressed through the project in both Norwegian psychological and medical journals [19-20], and will continue to be addressed through the project period to reach a wider audience. Raising the topic in mainstream media is also relevant. The PhD candidate and several members of the research environment have experience with public media appearances, project management and lecturing. A webpage for the project with information about the project and current research findings, is in progress. The project also plans for collection of data from the RCT at 24 months, to test if possible changes in function and quality of life persists over time.

Stakeholder	Content	Form of dissemination
Patients and parents/ guardians	New recommendations, research results and access to the developed intervention	Articles on hospital websites and social media. Information through HUHs Youth Council and User Committee, and relevant patient organizations.
Clinicians	Research results and new guidelines.	E-course and workshops for doctors at Helse Bergen and primary healthcare about the new intervention. New articles in Dagens Medisin and Tidsskrift for Norsk Psykologforening describing the results of the intervention. Presentation at national conference. Information through National Advisory Unit on Psychosomatic Disorders in Children and Adolescents, National alliance for health psychology in somatic healthcare, the Norwegian paediatric society and the Norwegian child and adolescent psychiatric society.
Research community	Research results, methodology	At least 4 publications in open access journals, such as BMC Health Services Research and BMC Complementary Medicine and Therapies. Presentations at national and international conferences, such as the National Psychology Congress and Global Nursing 2022. Attempt to participate in Researchers Grand Prix.
Politicians	Research results, recommendations	An updated briefing to the Norwegian ministry of health.
General public	Research results and new recommendations.	Debate article in Bergens Tidende and Aftenposten.

**Table 5.** Plan for dissemination to stakeholders

#### 4.5 Plans for Implementation

The implementation of the TpT-intervention has already started, and will continue both at HUH, Helse Vest and through the National Plan for Health and Hospital [15] who has already integrated some of the initial results. The project organization includes stakeholders among the hospital leaderships, who will be invited to participate in our strategy to generalize and disseminate results along with users and representatives from the community care and other hospital in the region. We wish to implement this intervention in all health trusts in Norway. This innovative interdisciplinary



intervention has the potential to transfer to other patient groups with complex health complaints, multi-referrals and multi-morbidity. The above mentioned plan for dissemination of results is made to aid the implementations of developed intervention for children with multiple referrals to specialist healthcare, and other relevant patient groups.

## 5. User Involvement

User involvement has been, and is, crucial in redesigning services to improve healthcare, functional level and prognosis for this patient group. The users in this project are primarily children, but also their families, the clinicians working with them (e.g doctors, psychologists and physiotherapists) and the leaders of the clinical institutions providing their healthcare. This project is based on feedback from families and clinicians working with these children. Parents have participated in designing the draft protocol for the study intervention and developing draft questionnaires to be used in the evaluation of the intervention. Clinicians (employees in both primary and secondary healthcare) have participated in workshops developing the draft protocol. Furthermore, all user groups will be invited to participate in the interpretation of findings, writing of the papers and discussions on how to translate and disseminate our results to improve present practice. Users are already involved in our project, and will continue to be so throughout the project. We believe that this involvement of users increases the quality and impact of our project, and constitute an important contribution in trying to redesign and improve healthcare for patients with complex health complaints.

Categories of users	Form of user involvement
Children with multiple referrals (target group)	Youth council participated in workshops and will be invited to participate in the interpretation and dissemination of results.
Parents of children in target group	User committee participated in workshops. Individual parents participated in development and pilot process, and will be invited to participate in the interpretation and dissemination of results.
Clinicians working with children in target group	Clinicians participate in workshops and will be invited to participate in the interpretation and dissemination of results.
Leaders of clinical institutions providing healthcare for children in target group	Leaders participate in workshops and pilot process.

**Table 6.** *User involvement by category*

## 6. Ethical Considerations

The Regional Committee for Medical Research Ethics has approved the intervention project (ID Number: 2018/344). The study is registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ID NCT04652154). Informed written consent is obtained from participants before inclusion in the study. Data used in the studies will be anonymized and saved at the research servers at Haukeland University Hospital (HUH). The study will be performed in accordance with the national and local regulatory legislation and requirements. All publication of findings will be «Open access», and anonymized data will be available from the authors upon reasonable request and with consent from the participants to make the data available to others.

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