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Evaluating the effects of parenting interventions for families with refugee backgrounds

Submission date	Recruitment status	[X] Prospectively registered
06/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/02/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/03/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study is an evaluation of parenting interventions for families who have relocated to Norway from non-Western-European countries. These interventions should strengthen parenting skills and confidence and reduce negative parenting practices. This should, in turn, result in better physical and mental development for their children. The parents will also give regular feedback to the professionals running the groups. This should improve mental health care by giving professionals timely feedback regarding their clients.

The primary aims of the study are to evaluate the effectiveness of parenting interventions and giving interventionists regular feedback for improving parenting skills, lowering parental stress, and reducing problem behavior in children. We will also evaluate whether parents with high levels of trauma or compromised mental health will benefit more from the interventions in general than parents with no trauma or mental health symptoms. We will also evaluate the potential protective factors that may lead to better outcomes for the parents.

Who can participate?
Families with a refugee background who have recently settled in Norway with one or more children between the ages of 6 and 12 years

What does the study involve?
Participants in the study will take part in one of two parenting groups, The Incredible Years or the International Child Development Program. These programs run once-per-week over the course of 12 to 15 weeks. The parents will fill out surveys at four points over the course of the study, as well as give weekly feedback to the program instructors about their progress.

For 40 parents, children and group leaders study participation will also include participation in qualitative interviews.

What are the possible benefits and risks of participating?
All newly arrived parents with refugee backgrounds in Norway must participate in a parenting

course as part of their settlement. It is therefore important to investigate how parenting programs work for this population. The results of the study have the potential to improve parenting practices, improve family dynamics, and lead to long-term benefits for society in the form of families with a refugee background who are better integrated into Norwegian society.

In the study, parents are to learn positive parenting practices.

The study examines how the programs are suited for the target group and what results are achieved with the initiative. The results will be useful and informative for the services and will benefit future refugees who come to Norway.

The refugee services and other relevant actors in the municipalities will gain increased knowledge and expertise related to the needs of newly arrived families, and about the use of parenting programs in the introduction program. With the project, the field will receive information on the effect of parenting interventions and a feedback system (MFS) in working with refugee parents.

All of the parents who participate will be compensated with a small stipend for their participation in the data collection. Additionally, families who participate in the study will fulfill their requirement to take a parent training course as part of their agreement with the Norwegian Immigration Authority.

Potential risks are relatively low and relate primarily to the amount of time it requires to participate. The actual filling out of the questionnaire and answering the questions are time-consuming for participants.

There a potential risk that interviews or/and questionnaires will retraumatize participants.

Contact with researchers and the project may, for some refugees, due to their background and history be distressing. Translators and link workers will hear about potentially sensitive information from research participants. There is a potential of stigmatization of parents participating in the study.

Despite the best efforts of the researchers, there is a small risk of sensitive data being shared inadvertently or opened by criminal means.

Where is the study run from?
UiT - The Arctic University of Norway (Norway), NTNU - RKBU Midt (Norway), RBUP East and South (Norway), and RKBU West (Norway)

When is the study starting and how long is it expected to run for?
January 2019 to December 2024

Who is funding the study?
Kavli Foundation (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
A69426

Study information

Scientific Title
Supported Parenting Interventions for Refugees and Minority Families (PIRM)

Acronym
PIRM

Study objectives
1. There will be no difference in parenting practices between the parents in The Incredible Years (IY) group and the International Child Development Program (ICDP) group after participation.
2. Measurement feedback will not significantly improve treatment outcomes for participants.
3. There will be no differences in outcomes for parents who report more anxious or depressive symptoms prior to treatment.
4. There will be no differences in outcomes for parents who report more traumatic or adverse life childhood events prior to treatment.
5. There will be no differences in outcomes for parents with high levels of resilience.
6. Participation in parenting interventions will not produce changes in parent resilience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/10/2019, the Regional Committees for Medical and Health Research Ethics – North (REK- Nord, UiT The Arctic University of Norway, Postboks 6050 Langnes, 9037 Tromsø; rek-nord@asp.uit.no; +47 77 64 61 40), ref: 2019/1116

Study design
This is a two-by-two factorial designed study with two randomized factors

Primary study design
Interventional

Secondary study design
2 x 2 Factorial and Mixed methods

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Parenting, parental stress, refugee parents, trauma, mental health condition, problem behavior in children

Interventions
This is a two-by-two factorial designed study with two randomized factors: parenting intervention and measurement feedback. The parenting factor is a randomized factor between The Incredible Years (IY) and the International Child Development Program (ICDP). The measurement feedback factor is a randomization of the parenting groups to using or not using

measurement feedback. The project is a multi-center collaboration and based in multiple municipalities throughout Norway. Participants in the study will be recruited from families with children and at least one parent has a refugee or minority background.

Families will be recruited at each participating site on an ongoing basis throughout the recruitment period and randomized to one of the two family interventions. The parenting groups will then be randomized to the Measurement Feedback System (MFS) condition (yes or no).

Parenting interventions:
1. The Incredible Years parenting program
2. The International Child Development Program
These programs are run weekly over the course of 12 to 15 weeks.

The app for use with the MFS is being developed in collaboration with the University of Oslo. The MFS app is used by families to enter data regarding their experience with the parenting intervention.

Data will be collected for the study at regular intervals during the period of recruitment. The interventions will be assessed using surveys collected at the pre-intervention baseline (T1), mid-intervention (T2), post-intervention (T3) and one-year follow-up (T4). The surveys will include instruments (listed under primary and secondary outcomes) for the parents to fill out. Qualitative interviews will be conducted with parents, children and/or group leaders post-intervention (T3).

Intervention Type
Behavioural

Primary outcome measure
Parenting practices of positive verbal discipline, harsh and inconsistent discipline, physical punishment, and praise and incentives measured using parenting practices inventory (PPI) at baseline (T1), 6 weeks (T2), 15 weeks (T3), and 1 year (T4)

Secondary outcome measures
1. Child behaviour will be measured using the Eyberg Child Behavior Inventory (ECBI) at baseline (T1), 6 weeks (T2), 15 weeks (T3), and 1 year (T4)
2. Parental distress will be measured using the Parenting Stress Index (PSI) at baseline (T1), 6 weeks (T2), 15 weeks (T3), and 1 year (T4)
3. Parent mental health will be measured using the Hopkins Symptom Checklist (SCL-10) at baseline (T1), 6 weeks (T2), 15 weeks (T3), and 1 year (T4)
4. Parent resilience will be measured using the Resilience Scale for Adolescents (READ) at baseline (T1) and 15 weeks (T3)
5. Parent adverse childhood experiences will be measured using the adverse childhood experiences (ACE) at 15 weeks (T3)

Overall study start date
01/01/2019

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Refugee and/or minority families
2. Families with ≥1 children between the ages of 6 and 12 years

Added 01/09/2020:
Participants in the study need to be able to speak or understand one of the following languages: Turkish, Somali, Arabic, Norwegian, English, French, Swahili or Tigrina

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
Parents with severe developmental delay

Date of first enrolment
01/03/2020

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Norway

Study participating centre
UiT - The Arctic University of Norway
UiT Norges arktiske universitet
Postboks 6050 Langnes
Tromsø
Norway
9037

Study participating centre

NTNU - RKBU Midt
RKBU Midt-Norge, NTNU
Postboks 8905 MTFS
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Study participating centre
RBUP East and South
Gullhaugveien 1-3
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Study participating centre
Norce, RKBU West
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Sponsor information

Organisation
The Arctic University of Norway

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Sponsor type
University/education

Website
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ROR
https://ror.org/00wge5k78

Funder(s)

Funder type
Charity

Funder Name
Kavli Foundation

Alternative Name(s)
The Kavli Foundation, Kavli Foundation (United States), Kavli

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
1. Planned publication of Rates of parental stress in refugee families compared with general population in Norway by 03/2022
2. Planned publication of Using the MFS, feedback from the practice field by 06/2022
3. Planned publication of Effectiveness of the IY intervention for refugee families in Norway by 12/2022
4. Planned publication of Additional effects of using a measurement feedback system to deliver parenting interventions to refugee families by 12/2022
5. Planned publication of Traumatic life events and the impact on treatment outcomes by 12 /2022
6. Planned publication of Parental mental health and their ability to respond to the needs of their child by 06/2023
7. Planned publication of Effective strategies of the IY program, a user-focused analysis by 06 /2023
8. Planned publication of Maintenance of treatment effects one year after treatment by 12/2023

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be stored in a publically available repository at https://dataverse.no/dataverse/uit. All instruments listed in the primary and secondary aims will be made available in anonymized format (with all primary and secondarily identifiable information removed) according to EU data protection regulations.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/11/2021	10/03/2023	Yes	No