Promoting adjustment and well-being of newly arrived immigrant adolescents (PIAYouth)

Submission date	Recruitment status	Prospectively registered
18/03/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/03/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
28/03/2024	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

Immigrant and refugee adolescents who migrate to a new country face acculturative challenges in addition to their ongoing developmental challenges. Nevertheless, most preventive interventions for recently arrived youth focus on a small segment of this population who may potentially be at risk for mental health issues related to psychological distress and past trauma. The PIA Youth Program was developed as a 6-week cognitive dissonance-based universal intervention to support newly arrived youth in promoting their adjustment and development in the host society. The program content was informed by the newly arrived youth's own description of needs and research on the risk and protective factors related to migration and resettlement processes. The program is delivered to groups of 3 to 6 recently arrived youth by trained leaders in the home language of participants or in Swedish. The youth engage in active discussions around potentially challenging acculturative and developmental issues, including learning (and improving) language, exploring the new environment, negotiating cultural differences, social interactions, seeking support, building a sense of belonging, and taking a stance for their future and setting goals.

Who can participate?

Adolescents between ages 12 and 16 years who migrated to Sweden after 2015.

What does the study involve?

The program uses the Dissonance-based Intervention (DBI) framework to and the content was informed by the results from a series of interviews with members of the target group. The intervention focuses on important themes such as learning the language, adaption to a new cultural environment, cultural differences, social connection and, belonging, handling challenges and seeking support, and setting up future goals. Each theme is covered in one of the six weekly meetings.

What are the possible benefits and risks of participating?

The participants of the PIA Youth Program have opportunities to discuss their acculturative and developmental challenges and how they can handle these challenges in constructive ways, and

motivate them to set goals for themselves. The pilot tests of this program showed that the youth found participation in the program enjoyable and the content of the discussions relevant and helpful for them to develop new perspectives.

The discussions do not focus on vulnerabilities, weaknesses, and negative emotions. Yet, talking about daily hassles and challenges may arouse negative emotional reactions in some participants. Therefore, the facilitators will be trained in communication skills and in recognizing discomfort in the participants. The participants are also informed that their participation is voluntary, and they can leave the session or the study at any time. The group leader and research leader serve as contact persons if participants feel the need to talk to someone after the session.

Where is the study run from? Örebro University (Sweden)

When is the study starting and how long is it expected to run for? January 2023 to December 2025

Who is funding the study?

- 1. Vetenskapsrådet (Sweden)
- 2. Forskningsrådet om Hälsa, Arbetsliv och Välfärd (Sweden)
- 3. VINNOVA (Sweden)

Who is the main contact?

Prof Metin Özdemir, metin.ozdemir@oru.se

Study website

https://www.piaprojektet.se

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2018-05756

Study information

Scientific Title

Cluster randomized controlled trial of the PIA youth program: promoting adjustment and well-being of newly arrived immigrant adolescents

Acronym

PIAYouth

Study objectives

- 1. How effective is the PIA Youth Program in promoting youth's confidence in achieving career and educational goals, persistence, optimism about future, motivation, and efficacy to learn Swedish, improve efficacy to seek support and attitudes towards mental health problems, and reduce anxiety about future and cultural clashes with parents at post-test and follow-up (primary outcomes)?
- 2. How effective is the PIA Youth Program in promoting youth's sense of societal belonging, views of Swedish society, motivation to acculturate, and ethnic identity-clarity at post-test and follow-up (secondary outcomes)?
- 3. What are the mechanisms that may explain the changes in youth's primary and secondary program outcomes?
- 4. Do the youth's initial levels of well-being, language anxiety, and sense of futility predict the program outcomes a post-test and follow-up?
- 5. Do the youth's initial levels of language anxiety, well-being, and sense of futility moderate the program outcomes a post-test and follow-up?
- 6. Do youth's sociodemographic background and migration-related experiences predict the program outcomes?
- 7. Do youth's sociodemographic background and migration-related experiences moderate the program outcomes?
- 8. What are the participants' own perspectives of their participation and the benefits of the program?
- 9. How does the program implementation process predict program outcomes for parents?
- 10. How do the characteristics of the program leaders predict their efficacy in implementing the program and program outcomes for the youth?
- 11. What are the predictors of satisfaction with the program, participation rate, and drop-out?
- 12. Is the PIA Youth Program cost-effective?
- 13. Other research questions concern youth's demographic characteristics, migration histories, experiences with the program and group leaders, program content, and potential iatrogenic effects.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 09/05/2023, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46-10-475 08 00; registrator@etikprovning.se), ref: 2023-01235-01

Study design

Interventional cluster randomized

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Promoting the adjustment and well-being of recently arrived immigrant adolescents in Sweden.

Interventions

The study is a cluster randomized controlled trial, in which schools (teaching school years 7, 8, and 9) are randomly assigned to (1) the PIA Youth Program (Active intervention), or (2) waiting-list control condition. The intervention groups are run either on-site (at the school) or online using video conferencing tools.

The PIA-Youth program is a group-based program to promote newly arrived refugee youth's adjustment and well-being. The program was developed based on Dissonance-based Intervention (DBI) framework and the content was informed by the results from a series of interviews with members of the target group. The intervention focuses on important themes such as learning the language, adaption to a new cultural environment, cultural differences, social connection and belonging, handling challenges and seeking support, and setting up future goals. Each theme is covered in one of the six weekly meetings.

The participants are recruited from schools, which are cluster randomized into:

- 1. The PIA Youth Program (Active intervention)
- 2. A waiting-list control condition

The program takes six weeks, with 6 weekly meetings that last 1.5 hours each. After 6 months of follow-up, participants attending the control schools are offered the intervention program. Participants in both conditions assessed at pre-test, six weeks after the pre-test (post-test) and 6 months after the pre-test (follow-up).

Intervention Type

Behavioural

Primary outcome measure

- 1. Confidence in achieving career goals is measured using two items. First item is asking youth to rate their confidence in achieving their career goal (0 to 100%) and the second item asks about the perceived difficulty to achieve their goal at pre-, post-, and follow-up.
- 2. Confidence in achieving educational goals is measured using two items. First item is asking youth to rate their confidence in achieving their educational goal (0 to 100%) and the second item asks about the perceived difficulty to achieve their goal at pre-, post-, and follow-up.
- 3. Persistence is measured 5 items of the Academic Persistence (AP) Scale at pre-test, post-test, and follow-up
- 4. Optimism was measured using an adapted version of the Optimism Scale (EPOCH) at pre-test, post-test, and follow-up.
- 5. Motivation to learn Swedish is measured using 6 items developed based on motivational theories on internal and external motivation at pre-test, post-test, and follow-up.
- 6. Perceived efficacy to learn Swedish is measured using 4 items developed based on Bandura's Self-efficacy Theory at pre-test, post-test, and follow-up.
- 7. Anxiety about future was measured using 6 items taken from the Hopelessness Scale for Children. The selected items measure hopelessness about future, and administered at pre-test, post-test, and follow-up.
- 8. Cultural clashes is measured using five items of Cultural Clashed between Child and Parents measure at pre-test, post-test, and follow-up
- 9. Efficacy for seeking help is measured using 6 items developed based on the enlisting social recourses subscale of Bandura's Children's Self-efficacy Scale at pre-test, post-test, and follow-up 10. Attitudes towards mental health problems is measured using from Self-Stigma Depression Scale at at pre-test, post-test, and follow-up

Secondary outcome measures

- 1. Sense of societal belonging is measured using the Adolescents' Societal Belongingness Scale (ASBS) at pre-test, post-test, and follow-up
- 2. View of Swedish society is measured using the Views about the Swedish Society Scale (VS) at pre-test, post-test, and follow-up
- 3. Motivation to acculturate is measured using the Acculturation Motivation (AM) measure at pre-test, post-test, and follow-up
- 4. Ethnic identity clarity is measured using 6 items adopted from the Self-Concept Clarity Scale at pre-test, post-test, and follow-up
- 5. WHO well-being index is measured using the Well-being Index by WHO (WHO-5) at pre-test, post-test, and follow-up
- 6. Language anxiety is measured using 3 items adopted from Motivation for Learning English scale at pre-test, post-test, and follow-up
- 7. Sense of futility is measured using the 4 item Sense of Futility Scale at pre-test, post-test, and follow-up

Overall study start date 01/01/2023

Completion date 31/12/2025

Eligibility

Key inclusion criteria

- 1. The youth immigrated to Sweden in 2015 or later
- 2. The youth is attending school grades 7 to 9
- 3. The youth is at between age 12 and 16 at the start of start of the program
- 4. The youth should be able to follow the programs in Swedish or in one of the other languages that the program materials are available: Arabic, Dari, Kurdish, Somalian, and Tigrinya.

Participant type(s)

Healthy volunteer, Learner/student

Age group

Child

Lower age limit

12 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

55 groups, with 3-6 participants in each group leading to N=165-330

Key exclusion criteria

Participants who self-report that they currently receive a treatment for a psychological problem or psychiatric illness

Date of first enrolment

01/05/2023

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

Sweden

Study participating centre

Örebro University

School of Behavioural, Social and Legal Sciences

Öгеbго

Sweden

70182

Sponsor information

Organisation

Örebro University

Sponsor details

Fakultetsgatan 1 Örebro Sweden 701 82 +46 19303000 registrator@oru.se

Sponsor type

University/education

Website

http://www.oru.se/English/

ROR

https://ror.org/05kytsw45

Funder(s)

Funder type

Government

Funder Name

Vetenskapsrådet

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)

Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

VINNOVA

Alternative Name(s)

Swedish Governmental Agency for Innovation Systems

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Results and Publications

Publication and dissemination plan

The results will be published in form of scientific papers in peer-reviewed journals. They will also be presented at conferences and reported back to the stake holders in various formats.

Intention to publish date

01/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Metin Ozdemir, metin.ozdemir@oru.se. Individual participant data regarding the primary and secondary outcomes collected during the trial will be shared after the deidentification and publication of the key studies. Data will be provided along with the study protocol and codebook to researchers who provide a methodologically sound proposal to achieve the aims in the approved research proposal and for individual participant data meta-analysis, given that there is no ethical and legal restriction. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary Available on request