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Rehabilitation of Afghans with disabilities impact evaluation

Submission date	Recruitment status	[_] Prospectively registered
28/07/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/08/2021	Other	

Plain English summary of protocol

Background and study aims
This Disability Program is the largest CBR program in Afghanistan. The program provides services to both children and adults with disabilities. The physiotherapy component targets physically disabled people, whereas people with mental, visual and hearing impairments are covered by the special and inclusive education component. Physiotherapy services are further offered to patients with back pain, temporal and non-permanent injuries or other conditions that potentially leads to impairment and disability. A continuing challenge is to make services available in remote areas, which will be able to satisfy the needs of persons with severe and permanent impairments. The aim of the study is to measure the impact of the various program activities on several outcomes: mobility, activities of daily living, communication, participation in social and community life, emotional well-being.

Who can participate?
People identified with an impairment living in the 169 villages where the program is active

What does the study involve?
The Disability Program delivers an extensive suite of services to Afghans with disabilities: physiotherapy, group training, loans, home based education, centre base education, inclusion in school, home based training, advocacy, and awareness.

What are the possible benefits and risks of participating?
The possible benefit for participating is improved quality of life. There is no risk of participating in the study, except possible limited emotional discomfort linked to some questions asked during interviews.

Where is the study run from?
Swedish Committee for Afghanistan (Afghanistan)

When is the study starting and how long is it expected to run for?
July 2012 to December 2015

Who is funding the study?
Swedish International Development Agency (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparing outcomes of Afghans with Disabilities (RAD) Community Based Rehabilitation programme (CBR) compared to controls with disabilities: a quasi-experimental study

Acronym
RADIE

Study objectives
The Community Based Rehabilitation program implemented in Afghanistan is increasing mobility, activities of daily living, communication, participation in social and community life and emotional well-being of participants with disabilities compared to controls with disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/12/2012, the Human Research Protection Office of Washington University in St Louis (Mailing Address: MS08089-29-2300, 660 S. Euclid Avenue, St. Louis, MO 63110, USA; tel not provided; HRPO@wustl.edu) ref: IRB ID #:201206117)
2. Approved 11/18/2012, Institutional Review Board of the Ministry of Public Health of Afghanistan (Masoud roundabout, Kabul; tel not provided; email not provided), ref: IRB ID#221643

Study design
Cluster quasi field experiment with a randomized control group

Primary study design
Interventional

Secondary study design
Quasi experiment, randomized control group

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
https://apps.who.int/iris/bitstream/handle/10665/39065/31922_guide1.pdf?sequence=2

Health condition(s) or problem(s) studied
Rehabilitation, education, employment and social participation of persons with disabilities

Interventions
The researchers did not randomize the participants in the CBR. They only carried out cluster randomization of the controls. This is why it is a quasi-experiment and not an RCT.

The inclusion criteria for the intervention group is the identification between January 2013 and December 2013 by 137 CBR workers of an individual with disabilities based on information from key informants in each mahal and word of mouth between residents. A person is categorized as disabled using a locally developed questionnaire based on the World Health Organization “Training in the community for people with disabilities: Guide for Local Supervisors” (World Health Organisation 1989). Each CBR worker assessed participant’s willingness to enrol in the CBR program and consent to participate in the study. Each CBR worker averages two new participants per month. 1680 individuals were enrolled in 169 villages or urban areas called Mahals. They are catchment areas of a given CBR worker. The size of each mahal depends on the number of persons with disabilities living in the area and enrolled in the program that one given

CBR worker is able to serve. New participants above age three were interviewed using the capability tool within a month of commencing services with a CBR worker.

The Community Based Rehabilitation program includes five components:
1. Social integration of people with disabilities
2. Employment support and vocational training
3. Special and inclusive education
4. Physiotherapy and orthopedic services
5. Institutional capacity development

The CBR program is implemented in 13 provinces and 48 districts of northern and eastern Afghanistan. The program offers several services:
1. Physiotherapy
2. Group training
3. Loans
4. Home-based education
5. Centre base education
6. Inclusion in school
7. Home-based training
8. Advocacy
9. Awareness

The intervention varies between 6 months and 3 years depending on the complexity of the needs of the participants. Some interventions continue after the end-line interview.

The control group receive usual healthcare services provided by the basic package of healthcare services of the Ministry of Public Health, which is offered to the general population.

Intervention Type
Mixed

Primary outcome measure
Measured at baseline (entrance in the program between 01/07/2012 and 31/12/2013), midline (after 1 year in the program between 01/07/2013 and 31/12/2014) and endline (after 2 years in the program between 01/07/ 2014 and 31/12/2015):
1. Mobility measured using a mobility index composed of five activities with response choices limited to a Likert scale composed of three choices (I can always, I can with help, I cannot at all): Can you sit (asked to respondents above 1 year old); Can you stand (above 1 year old); Can you move inside the home (above 1 year old); Can you move outside the home (above 2 years old); Can you walk at least ten steps (above 2 years old).
2. Activity of daily living outcome measured using an index composed of four activities with the same three response choices: Are you able to eat on your own (asked above 4 years old); Are you able to bathe (above 8 years old); Are you able to use the latrine (above 3 years old); Can you dress and undress (above 4 years old).
3. Communication measured by an index focused on the four following functions with the same three response choices: Can you speak (above 2 years old); Can you understand simple instructions (above 2 years old); Can you express needs (above 2 years old); Do you feel confident learning new things (above 4 years old).
4. Social participation measured using an index comprised a first item below with three response choices (I can without difficulty, I can with some difficulties, no, I cannot at all) and four following items with three different choices (I can always, I can sometimes, no never): Can you make

friends outside the family; Are you consulted in family decisions (above 15 years old); Can you join in community activities and ceremonies; Do you feel respected in the community (above 5 years old); Do you feel respected in your family.
5. Emotional well-being measured using an index was composed of five items with three response choices (never, sometimes, always): Do you feel sad (above 5 years old); Do you feel angry (above 5 years old); Do you feel worried or distressed (above 5 years old); Do you have nightmares or bad sleep (above 5 years old); Do you have headaches, stomach-aches or nausea (above 5 years old)

Secondary outcome measures
Employment measured using a question about paid activity in the last week at baseline (entrance in the program between July 1st 2012 and December 31st 2013), midline (after one year in the program between 1st July 2013 and 31st December 2014) and endline (after two years in the program between 1st July 2014 and 31st December 2015)

Overall study start date
01/11/2011

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Screened as having a disability using a locally developed, tested and validated questionnaire based on World Health Organization guidelines for grass root disability program to account for contextual factors
2. Joining the CBR program between July 2012 and December 2013
3. Living in one of the 169 villages or urban areas called mahals of the catchment area of the program
4. Willingness of the person with disabilities and the family members to participate in the CBR programs
5. Readiness of a family member to be trained by - and implement - the activities set up by the CBR worker in order for such activities to be ongoing daily, while the CBR worker would check progress made on a weekly or sometimes bi-weekly basis
6. Absence in the mahal of a similar intervention by any other organization
7. Intervention is welcomed by the overall village community and particularly the village council or Shurah

Participant type(s)
Other

Age group
All

Sex
Both

Target number of participants
1,680 participants, number varies per cluster, 169 clusters

Total final enrolment
1861

Key exclusion criteria
1. Refused to participate in the program
2. Not living in one of the villages covered by the program
3. Not disabled

Date of first enrolment
01/07/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Afghanistan

Study participating centre
Swedish Committee for Afghanistan
Kabul Management Office
PO Box 27027
Kabul
Afghanistan
1001

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01yc7t268

Funder(s)

Funder type
Government

Funder Name
Swedish International Development Agency

Funder Name
Swedish Committee of Afghanistan

Funder Name
Washington University in St. Louis

Alternative Name(s)
WashU, Universitas Washingtoniana, Eliot Seminary, Washington University in STL, Washington Institute, Washington University, WUSTL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan

Data collected for the study, including deidentified individual participant data and a data dictionary defining each field in the set will be made available to others at publication. The data will be made available in the DRYAD repository at https://datadryad.org/stash with investigator support, after approval of a proposal, with a signed data access agreement.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/08/2020	No	No
Results article		21/08/2021	23/08/2021	Yes	No