Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Community Based Rehabilitation (CBR) on Quality of Life and Psychological Well-being of Children Enrolled in Special Education Institutes

Protocol summary

Study aim
To check the prevalence of Quality of Life (QoL) and Psychological Well-being among all the categories of disabilities and their parents or caregivers. To evaluate whether the Quality of Life (QoL) and Psychological Well-being of disabled children and their parents or caregivers can be improved through Community Based Rehabilitation (CBR) services.

Design
Community based, randomised controlled trial of 160 participants, control and experimental.

Settings and conduct
An experimental design will be used. Section one will be comprised of demographics; the second section will contain the screening questionnaires that will be pre-tested among both groups; and in the third level, there will be training and workshops of CBR strategies This entire process will take approximately three months.

Participants/Inclusion and exclusion criteria
Disabled children enrolled in special education institutes at mild level with all the categories i.e., physically disabled, hearing impaired, visually impaired, and mentally challenged are included. All other children with severe disabilities or no disabilities are excluded.

Intervention groups
1. Defining the Community or Special Institutes 2. Entering into the community 3. Selection of volunteers. 4. Vocational Strategy in CBR. 5. Training resources and content. 6.Training and the use of local resources. 7. Transfer of knowledge and skills within the community. 8. Intervention and Referrals

Main outcome variables
Quality of Life (QoL) and Psychological Well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221016056196N1**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**

Registration date
2022-11-09, 1401/08/18

Registrant information

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Name of organization / entity
The Islamia University of Bahawalpur
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Pakistan
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-10, 1401/08/19

Expected recruitment end date
2023-02-10, 1401/11/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectiveness of Community Based Rehabilitation (CBR) on Quality of Life and Psychological Well-being of Children Enrolled in Special Education Institutes

Public title
Effectiveness of Community Based Rehabilitation (CBR) on Special Education Children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Disabled children enrolled in special education institutes at mild levels with all the categories, i.e., physically disabled, hearing impaired, visually impaired, and mentally challenged. Disabled children and their caregivers of all religions, genders, and socioeconomic status. School-level disabled children.
Exclusion criteria:
All other children with severe disabilities or no disabilities. Disabled children above 17 years. Children with mental disorders like schizophrenics, panic or mood disorders, etc. Disabled children and their caregivers outside of the enrollment in special education institutes of Bahawalpur District.
Age
To **17 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
For the generalizability of this study results, and to cover the area of Bahawalpur Division the multistage sampling technique will be used (Raver, Gershoff, & Aber, 2007). Following steps will be employed to proceed: Stage 1. Selection of strata (Institutes in city or tehsil). The population will break up into strata by Institutes of Special Education in city or tehsil in Bahawalpur District will be selected. Stage 2. Selection of students from each sampled Institutes of Special Education. On 2nd stage, total No. of students in selected strata will be identified and then enrolled special students will be selected from each category of disability as per proportion of students (see figure 2.2). Enrolled students of Special Education Institutes and their parents or caregivers from Bahawalpur District will be the part of this research.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of The Islamia University of Bahawalpur
Street address
The office of the Research, Innovation and Communication (ORIC), The Islamia University of Bahawalpur, Baghdad-ul-jadeed Campus
City
Bahawalpur
Postal code
63100
Approval date
2022-10-10, 1401/07/18
Ethics committee reference number
2044/PSY

2

Ethics committee
Name of ethics committee
Ethics Committee of Department of Special Education
Street address
District Education Officer, Special Education, Hasilpur Road, Bahawalpur
City
Bahawalpur
Postal code
63100
Approval date
2022-10-10, 1401/07/18
Ethics committee reference number
DEO(Spl-Edu)/Bwp/22/221

Health conditions studied

1

Description of health condition studied
Hearing Impaired Children
ICD-10 code
H90
ICD-10 code description
Conductive and sensorineural hearing loss

2

Description of health condition studied
Visually Impaired Children
ICD-10 code
H54
ICD-10 code description
Blindness and low vision

3

Description of health condition studied
Physically Handicapped Children
ICD-10 code
R29
ICD-10 code description
Other symptoms and signs involving the nervous and musculoskeletal systems

4

Description of health condition studied
Mentally Challenged Children
ICD-10 code
F70
ICD-10 code description
Mild intellectual disabilities

Primary outcomes

1

Description
Quality of Life (QoL) and Psychological Well-being
Timepoint
3 months after intervention
Method of measurement
The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) to measure Psychological Well being, World Health Organization Quality of Life (WHOQOL) to measure Quality of Life (QoL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training and workshops on CBR strategies will be arranged for the experimental group. These workshops will be conducted at regular intervals of one week for the disabled children and their parents/caregivers. In these workshops, the experimental group will not only learn about the facilitative strategies for disabled children but also address the intervening issues. The procedure of CBR intervention will comprised of 3 months (12 weeks). Besides, the 128 members of the experimental group, children's family members, and other community members will also be involved in these rehabilitation programs.
Category
Rehabilitation

2

Description
Control group: No any Intervention will be given to control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Division Bahawalpur
Full name of responsible person
The District Education Officer
Street address
Bahawalpur Division, Punjab, Pakistan
City
Bahawalpur
Postal code
63100
Phone
+92 62 2505252
Email
deosebwp5@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Special Education Institutes, Bahawalpur Division
Full name of responsible person
District Education Officer
Street address
The District Education Office, Hasilpur Road, Bahawalpur, Pakistan
City
Bahawalpur
Postal code
63100
Phone
+92 62 2505252
Email
deosebwp5@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Investigator Initiated
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
The Islamia University of Bahawalpur
Full name of responsible person
Areeba Ather Malik
Position
Ph.D Student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Effectiveness of Community Based Rehabilitation (CBR) on Quality of Life and Psychological Well-being of Children Enrolled in Special Education Institutes
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
for academic institutions, community
Under which criteria data/document could be used
Email id: areebawaseem5@gmail.com
From where data/document is obtainable
Email Id: areebawaseemd@gmail.com
What processes are involved for a request to access data/document
Follow email address
Comments