

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Areeba Ather Malik

Name of organization / entity

The Islamia University of Bahawalpur

Country

Pakistan

Phone

+92 345 5112494

Email address

fa19e1pa009@iub.edu.pk

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

Street address

House no 5/A, Awais Block, Sajid awan colony,
Bahawalpur, Pakistan

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 345 5112494

Email

areebawaseemd@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The Islamia University of Bahawalpur

Full name of responsible person

Areeba Ather Malik

Position

Ph.D Student

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Fax**Email**

areebawaseemd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The Islamia University of Bahawalpur

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Fax**Email**

areebawaseemd@gmail.com

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