

Evaluation of MATCH - modular approach to therapy for children with anxiety, depression, trauma and conduct problems

Submission date 08/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/02/2016	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/11/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mental health problems are common in both children and teenagers and approximately 50% of all adult mental health disorders begin in adolescence. In general, evidence-based psychotherapies (treatments) for patients in this age group has not been widely used in Norway. One possible reason for this is that these treatments are not considered either flexible and robust enough to meet the needs of youths in everyday clinical practice. In particular, comorbidity (i.e. other health issues) and changing problems and needs during treatment have been pointed out as obstacles for the use of evidence-based psychotherapies. The Modular Approach to Therapy for Children with Anxiety, Depression, Trauma or Conduct Problems (MATCH) is a training programme made up of a number of treatment modules that address different problems, including anxiety, depression, trauma-related symptoms and disruptive behaviour, as well as cater for co-morbidities. This study is looking at testing how effective MATCH is as helping children and adolescents with their mental health problems compared with those that receive the usual treatment. Long term effects of the treatment are also going to be investigated.

Who can participate?

Therapists at one of the seven child and Youth Psychiatric outpatient clinics taking part in this study. Patients taking part must be aged between 6 and 14.5 years old and referred to psychiatric treatment due to problems with depression, anxiety, trauma or behavioural issues.

What does the study involve?

Therapists are randomly allocated to one of two groups. Those in group 1 are given 5 days training in MATCH. They then treat their young patients using this programme. Therapists in group 2 are not given training in MATCH treat their patients as usual. Both children taking part in the study and their caretakers (for example, parents) are asked to fill in questionnaires that will help researchers assess their mental health before the therapy starts and then at 3, 6, 9, 12, 18 and 24 months after therapy starts.

What are the possible benefits and risks of participating?

This study could further researchers understanding of what helps youths suffering from anxiety, depression, trauma and/or behavioural problems. Participants might find it meaningful to contribute to this. However, the families that participate in the study will be offered therapy that is not sufficiently tested in Norway. It could be argued that there are ethical problems related to this. The researchers running this study also know very little about what "treatment as usual" actually consists of, and the observation data (video films of the therapy) will help them understand more of this. Another potential ethical dilemma is that responding to questionnaires, that are both rather time consuming and asking sensitive questions, may be a burden. The participants will receive a moderate economical compensation for the time spent answering questionnaires. They are also informed that all participation is voluntary and that they can withdraw from the study at any time. The participants that withdraw from the study will still continue receiving treatment for as long as the therapist considers it necessary/helpful.

Where is the study run from?

Seven child and youth psychiatric outpatient clinics in Norway.

When is the study starting and how long is it expected to run for?

January 2015 to September 2024

Who is funding the study?

The Norwegian Center for Child Behavioral Development

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomized controlled effectiveness study of modular approach to therapy for children with anxiety, depression, trauma and conduct problems (MATCH)

Acronym

MATCH

Study objectives

1. We will investigate whether participants in the MATCH group will have a larger reduction in internalization and externalization problems compared to the treatment as usual group at the end of treatment
2. We will investigate whether participants in the MATCH group will have a more rapid reduction in internalization and externalization problems compared to the treatment as usual group.
3. We will investigate whether participants in the MATCH group will have a larger reduction in internalization and externalization problems compared to the treatment as usual group at follow-up (2 years after start of therapy)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional committees for medical and health research ethics, 03/08/2015, ref: 2015/633-1

Study design

Multi-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Depression, anxiety, trauma and conduct problems in young people and children

Interventions

1. Modular approach to therapy for children with depression, anxiety, trauma and conduct problems (MATCH)

Therapists will be given a manual, trained and follow consultation in MATCH. They will receive 5 days of training in MATCH and will after starting their first study cases have weekly Skype/Lync consultation sessions with a MATCH trainer. This is a modular approach to therapy for children which consists of modules from cognitive behavioral therapy and parental training. MATCH was specifically designed to combine the effective elements of the evidence based therapies (EBTs) for anxiety, depression, trauma-related symptoms and disruptive behaviour in one protocol, cater for co-morbidity and provide an opportunity to address different disorders that may emerge during therapy. A web based system (PATH) will provide the therapists with weekly data on changes in the severity of the patients problems, which will guide the therapists choice of modules for subsequent sessions. All sessions are done face-to-face and are one-on-one with the child or his/her family.

2. Treatment as usual

Any therapist who is not trained in MATCH and is currently working in the Child and Youth Psychiatric clinics (Barne- og ungdomspsykiatriske klinikker) used in the study will be able to provide control cases.

Intervention Type

Behavioural

Primary outcome measure

1. Youth Self-Report Form (YSR). This is a child-report measure that assesses problem behaviors, and that provides scales for internalizing and externalizing problems. It also scores eight empirically based syndromes and DSM-oriented scales, and provides a summary of total problems. Measured before therapy starts, and 3, 6, 9, 12, 18 and 24 month after therapy starts.
2. Child Behavior Checklist (CBCL). This is a parallel form to the YSR where caretakers are the respondents. Measured before therapy starts, and 3, 6, 9, 12, 18 and 24 month after therapy starts.

Every week during therapy the participants and their parents will answer a mail survey including:

1. Top problems assessment: rating of the severity of three "top problems" which are defined by the participant at the start of therapy.
2. Behavior and emotions survey – child: Child self report of behavior and emotions/thoughts (measure of internalizing and externalizing problems)
3. Behavior and emotions survey – parent: Parent report on child's behavior and emotions /thoughts (measure of internalizing and externalizing problems)

Secondary outcome measures

1. Use of other services and medication. This will be measured with a questionnaire inspired by Service Assessment for Children and Adolescents (SACA). The items in this version are chosen so that they would span most of the therapeutic and pedagogical services a child/adolescent in Norway could be offered.

Potential moderators and mediators:

1. Action and Acceptance Questionnaire (parent)
2. SCL5 (parent)
3. Observational data (all therapy sessions will be filmed, and a random selection of these will be rated to obtain a measure of fidelity and therapist/client-alliance)

- 4. Therapist background
- 5. Implementation

Overall study start date

01/01/2015

Completion date

01/09/2025

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 21/12/2023:

1. From 6 to 14.5 years
2. Referred to psychiatric treatment due to problems with depression, anxiety, trauma or conduct.

Previous participant inclusion criteria:

1. From 6 to 14 years
2. Referred to psychiatric treatment due to problems with depression, anxiety, trauma or conduct.

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

14.5 Years

Sex

Both

Target number of participants

280

Total final enrolment

121

Key exclusion criteria

1. Psychosis, intellectual disability, pervasive developmental disorder, anorexia, bulimia or having conducted sexual abuse.
2. Acute suicidality, or suicide attempt within the past 12 months.
3. Referred to psychiatric treatment solely due to inattention and/or hyperactivity.

4. Repeated and grave antisocial and criminal behavior (e.g. serious treats to hurt others, vandalism, burglary, or violence).

5. Substance abuse as primary problem

Date of first enrolment

15/01/2016

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Norway

Study participating centre

Child and Youth Psychiatric outpatient clinic - Follo

Ski

Akershus

Norway

1400

Study participating centre

Child and Youth Psychiatric outpatient clinic - Øvre Romerike

Norway

2050

Study participating centre

Child and Youth Psychiatric outpatient clinic - Hamar

Norway

2321

Study participating centre

Child and Youth Psychiatric outpatient clinic - Voss

Norway

5700

Study participating centre

Child and Youth Psychiatric outpatient clinic - Nordhordaland

Norway

5914

Study participating centre
Child and Youth Psychiatric outpatient clinic - Bergen Sentrum
Norway
5021

Study participating centre
Child and Youth Psychiatric outpatient clinic - Ytrebygda
Norway
5221

Sponsor information

Organisation
The Norwegian Center for Child Behavioral Development

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Sponsor type
Research organisation

Website
<https://www.nubu.no>

ROR
<https://ror.org/05tas6715>

Funder(s)

Funder type
Research organisation

Funder Name
The Norwegian Center for Child Behavioral Development

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 21/12/2023:
Approximate publication plan is below:
2024: A Randomized Effectiveness Trial of Modular Approach to Therapy for Children (MATCH)

Previous publication and dissemination plan:
Approximate publication plan is below:
2019: A Randomized Effectiveness Trial of Modular Approach to Therapy for Children (MATCH): Immediate outcomes
2021: A Randomized Effectiveness Trial of Modular Approach to Therapy for Children (MATCH): 2-year Follow-Up after intake
2020-2022: Effects of Modular Approach to Therapy for Children (MATCH) – moderators and mediators (implementation, fidelity, family background, etc)

Intention to publish date

01/12/2024

Individual participant data (IPD) sharing plan

Current IPD sharing plan as of 21/12/2023:
The data are not publicly accessible due to the small sample size and sensitivity of the data.

Previous IPD sharing plan:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/01/2019		Yes	No
Results article		18/10/2024	21/10/2024	Yes	No