ISRCTN24678005 https://doi.org/10.1186/ISRCTN24678005

Psychotherapy in paediatric patients with quiescent inflammatory bowel disease

Submission date
07/04/2023

Recruitment status
No longer recruiting

Registration date
14/04/2023

Overall study status
Completed

Last Edited
04/01/2024

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inflammatory bowel diseases (IBD) are chronic and pervasive conditions of the gastrointestinal tract with a rising incidence in paediatric and young adult populations. Evidence suggests that psychological disorders might be associated with relapse of disease activity. This study aims to evaluate the effectiveness of Brief Psychodynamic Psychotherapy in addition to standard medical therapy (SMT) in maintaining clinical remission in adolescents and young adults with quiescent (inactive) IBD, compared to SMT alone.

Who can participate?
Patients aged 11 to 21 years with quiescent IBD

What does the study involve?
Participants are randomly allocated into two groups: the first group completes eight sessions of psychotherapy in addition to their current medical treatment, and the second group continues their current medical therapy. The rate of youths who have quiescent disease is measured 1 year later.

What are the possible benefits and risks of participating?
Possible benefits include prolonged times of remission of the disease and fewer hospitalizations. There are no risks to the participants.

Where is the study run from?
Bambino Gesù Children's Hospital (Italy)

When is the study starting and how long is it expected to run for?
September 2019 to December 2022

Who is funding the study?
Bambino Gesù Children's Hospital (Italy)

Who is the main contact?
Dr Francesco Milo, francesco.milo@opbg.net (Italy)

Contact information

Type(s)
Public

Contact name
Dr Francesco Milo

ORCID ID
https://orcid.org/0000-0003-2746-4086

Contact details
Bambino Gesù Children's Hospital
Piazza S. Onofrio 4
Rome
Italy
00165
+39 (0)668592228
francesco.milo@opbg.net

Type(s)
Principal investigator

Contact name
Dr Paola Tabarini

ORCID ID
https://orcid.org/0000-0002-2146-4176

Contact details
Bambino Gesù Children's Hospital
Piazza S. Onofrio 4
Rome
Italy
00165
+39 (0)668592228
paola.tabarini@opbg.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2857

Study information

Scientific Title
Psychodynamic psychotherapy in adolescents and young adults with quiescent inflammatory bowel disease: a randomised clinical trial

Study objectives
It is hypothesized that psychodynamic psychotherapy + Standard Medical Therapy would be superior to Standard Medical Therapy alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/07/2022, Ethics Committee Bambino Gesù Children's Hospital (Piazza S. Onofrio 4, 00165, Rome, Italy; +39 (0)6 6859 2572 – 3580; comitato.etico@opbg.net), ref: 2857_OPBG_2022

Study design
Single-centre two-arm interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adolescents and young adults (AYA) with quiescent inflammatory bowel disease (IBD), Crohn's disease (CD) and ulcerative colitis (UC)

Interventions
On completion of the baseline Information Report Form (IRF), each recruited participant will be randomly allocated to either the treatment or control arm . A data analyst not actively involved in the recruitment process performed the randomization. Randomization will use a 1:1 allocation ratio and will follow a computer-generated randomization sequence that will be generated using Stata version 17 or later.

Participants randomized to the STPP intervention group will receive structured individual therapy delivered by a psychodynamic psychotherapist with advanced post-graduate training based in the outpatient clinic, with weekly briefing sessions to disclose difficulties perceived by the patients/therapists or define additional treatment adaptations. Eight 50-60-minute weekly sessions over a period of 8 weeks will be offered. The sessions will be delivered face-to-face and based in the outpatient clinic.

The intervention was developed specifically for this project and was based on psychodynamic principles and adapted for the psychosocial needs of individuals with IBD. To ensure the trustworthiness of the intervention, two psychodynamic psychotherapists with advanced post-graduate training performed all interventions.

Participants in the control group will receive a “standard medical therapy”, consisting of the continuation of the current medical therapy and regular medical consultations of 15–30 min with the (paediatric) gastroenterologist every 3 months, in which overall well-being, disease activity, and future diagnostic/treatment plans were discussed.

The study's primary outcome is remission maintenance: the proportion of participants with steroid-free remission at week 52 (1 year) between the two treatment groups. Disease activity is measured according to the PCDAI score for patients with CD and the PUCAI score for those with UC. Active disease is defined as a score ≥ 10 on PCDAI / PUCAI scores and the presence of levels of elevated inflammatory markers (e.g. C-reactive protein levels ≥ 8 mg/L and faecal calprotectin level ≥75 µg/g) combined with endoscopic inflammatory findings. A paediatric gastroenterologist, who is blinded about participants' allocation, performed disease activity assessment by reviewing patients' electronic health records.

The study's secondary outcomes comprise the assessment of healthcare utilization between the two groups, using the frequency of hospitalizations over the next 52 weeks after baseline and adherence to medication. Participants are labelled "adherent" if they follow all prescribed medication in the period of 52 weeks after baseline; otherwise, they are labelled "non-adherent". The difference in adherence is evaluated by comparing the proportion of "adherent" and "non-adherent" patients between the two groups.

Intervention Type
Behavioural

Primary outcome(s)
Remission maintenance: the proportion of participants with steroid-free remission defined by disease activity and measured using the Pediatric Crohn's Disease Activity Index (PCDAI) score for patients with CD and the Pediatric Ulcerative Colitis Activity Index (PUCAI) score for those with UC from baseline to week 52

Key secondary outcome(s))
1. Healthcare utilization measured using the frequency of hospitalizations recorded in patient medical records from baseline to week 52
2. Adherence to medication measured by quantifying adherent and non-adherent participants recorded in patient medical records from baseline to week 52

Completion date
15/12/2022

Eligibility

Key inclusion criteria
1. IBD patients aged between 11 and 21 years old
2. Able to read, write, and speak Italian language
3. Without expectation of surgery in the upcoming 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
11 years

Upper age limit
21 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Severe cognitive, neurological and psychiatric co-occurring conditions that could interfere with patients' participation
2. Inability to provide informed consent and receiving psychological treatment or psychotropic medication at the time of recruitment (or other psychotropic medication <2 years before recruitment)

Date of first enrolment
09/09/2021

Date of final enrolment
09/12/2021

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale Pediatrico Bambino Gesù IRCCS
Piazza S. Onofrio 4
Roma
Italy
00165

Sponsor information

Organisation
Bambino Gesù Children's Hospital

ROR
https://ror.org/02sy42d13

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ospedale Pediatrico Bambino Gesù

Alternative Name(s)
Bambino Gesù Children's Hospital, Baby Jesus Paediatric Hospital, Bambino Gesù Pediatric Hospital, Bambino Gesù Children's Hospital of Rome, Pediatric Hospital Bambino Gesù, Bambino Gesù Hospital, OPBG

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from Francesco Milo (francesco.milo@opbg.net)
The type of data that will be shared: anonymized raw data in the Excel file
Timing for availability: 4 weeks
Whether consent from participants was required and obtained: prior to recruitment during outpatients' visits
Comments on data anonymization: data were anonymized and the file was encrypted before all data analysis

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/08/2023	03/01/2024	Yes	No
Basic results		04/01/2024	04/01/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes