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Psychological intervention to improve the mental health of patients with COVID-19

Submission date
22/06/2020

Recruitment status
No longer recruiting

Registration date
01/07/2020

Overall study status
Completed

Last Edited
17/11/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
As a public health emergency of international concern, the COVID-19 outbreak has resulted in a significant burden on health systems as well as economic development, along with a significant impact on individual's physical and psychological health. The number of infected and confirmed cases increased rapidly in a short period due to a lack of knowledge of this new infectious disease, of which more 80% were patients with mild symptoms. The existing research also highlights that patients with COVID-19 suffer high levels of anxiety, depression, loneliness, despair and anger, which can further develop into severe mental disorders such as acute stress disorder (ASD) and post-traumatic stress disorder (PTSD). A small number of patients demonstrate extreme psychological behaviours during the COVID-19 pandemic, such as blaming, abusing medical staff and tearing up protective equipment, which exposed front-line medical staff to a higher risk. In addition, multiple studies have documented that without timely psychological intervention and assistance, psychological symptoms such as anxiety and depression can further develop into severe mental disorders such as acute stress disorder (ASD) and post-traumatic stress disorder (PTSD). Therefore, effective psychological intervention at the early stages of COVID-19 is important for patients.
Cognitive behavioural therapy (CBT) as evidence-based psychotherapy has been widely used in the treatment and prevention of physical and psychological distress in both the community and inpatients. It aims to help individuals to identify stress levels and modify negative cognitive beliefs and behaviours, reduce or eliminate symptoms of psychological distress, and further help individuals back to their normal life in terms of psychological and social functions.
The aim of this study is to apply CBT to patients with COVID-19, and examine the effectiveness of CBT in relieving patients' psychological distress during the COVID-19 pandemic.

Who can participate?
Patients aged 20-69 with COVID-19 who had mild symptoms in line with the diagnostic criteria of the Chinese Management Guidelines for COVID-19 (version 6.0)

What does the study involve?
Participants will be randomly assigned to either the intervention group and the control group. The control group receive routine treatment according to the Chinese Management Guidelines for COVID-19 (including antiviral treatment, symptomatic treatment of fever and nursing care),

while participants in the intervention group receive routine treatment with additional CBT. Participants will be asked to complete an assessment before and after the intervention to assess the effectiveness of the CBT intervention in terms of reducing depression, anxiety and stress levels.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the CBT intervention may help to reduce patients' depression, anxiety and stress, and to improve their psychological health. There are no known risks to participants taking part in this study.

Where is the study run from?
The First Affiliated Hospital of Bengbu Medical College (China)

When is the study starting and how long is it expected to run for?
February 2020 to March 2020

Who is funding the study?
Bengbu Medical College (China)

Who is the main contact?
Prof. Jin Zhi Li
2639917769@qq.com

Contact information

Type(s)
Scientific

Contact name
Prof Jinzhi Li

ORCID ID
https://orcid.org/0000-0002-4372-2340

Contact details
No 2600, Donghai Avenue
Bengbu
China
233030
+86 (0)552 3175212
2639917769@qq.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of cognitive behavioural therapy on depression, anxiety and stress in patients with COVID-19: a randomized controlled trial

Study objectives
The COVID-19 outbreak has had a tremendous impact on patients' psychological health. They suffer high levels of anxiety, depression, loneliness, despair and anger. Cognitive Behavioural Therapy (CBT) can reduce patients' depression, anxiety and stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/02/2020, Ethics Committee of the First Affiliated Hospital of Bengbu Medical College (No.287, Changhuai Road, Bengbu City, Anhui Prov, China, 233000; +86 (0)552 3086046; no email address), ref: BYYFY-2020KY10

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression, anxiety and stress in patients with COVID-19 (SARS-CoV-2 infection)

Interventions
Ninety-three eligible participants selected by cluster sampling are randomized to an intervention group (n = 47) and a control group (n = 46) using a computerized random number generator by a trial statistician who had no clinical involvement in the project.

Participants in the control group receive routine treatment according to the Chinese Management Guidelines for COVID-19, while participants in the intervention group receive routine treatment with additional CBT.

The cognitive intervention includes:
1. Providing information related to COVID-19, real-time information on the COVID-19 outbreak
2. Giving clear and comprehensive explanations to patients' questions

The behaviour intervention includes:
1. Instruction on self-protection behaviours such as proper hand-washing technique
2. Self-monitoring COVID-19 related symptoms

3. Relaxation techniques such as music therapy and breath meditation
4. Encourage patients to maintain close communication with family and friends through a mobile phone or WeChat (a communication app)

The CBT intervention is performed once a day in the morning, taking 30 minutes to complete and is recorded by the nurses. Each intervention is strictly carried out through face-to-face communication, with a patient-centred approach so the intervention could be adjusted based on the individual's needs.

The duration of intervention ranged from 7 to 29 days.

Intervention Type
Behavioural

Primary outcome(s)
Psychological health level of the patient with COVID-19, assessed using the Chinese Version of Depression Anxiety and Stress Scale-21 (DASS-21) for all participants at baseline and post-intervention (1 day later)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
22/03/2020

Eligibility

Key inclusion criteria
1. Patients with COVID-19 who had mild symptoms in line with the diagnostic criteria of the Chinese Management Guidelines for COVID-19 (version 6.0)
2. Good communication and understanding of Chinese
3. Aged 20-69 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
93

Key exclusion criteria

1. Previously diagnosed with depression and currently taking medication
2. Prior cognitive dysfunction
3. Experienced another major stressful event (e.g. divorce, bereavement) in the past year

Date of first enrolment
10/02/2020

Date of final enrolment
22/03/2020

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Bengbu Medical College
Department of Infectious Diseases
No. 287, Changhuai Road
Bengbu City
Anhui Prov
Bengbu
China
233000

Sponsor information

Organisation
Bengbu Medical College

Funder(s)

Funder type
University/education

Funder Name
Bengbu Medical College

Alternative Name(s)
, BBMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as it is stipulated in the informed consent signed with the patient that any information of the participants will not be disclosed, and the dataset compiled for this study will be kept and stored by the first author.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/10/2020	17/11/2020	Yes	No