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Life Review Therapy for Holocaust Survivors: A study to evaluate the efficacy of a treatment

Submission date
31/03/2018

Recruitment status
No longer recruiting

Registration date
26/04/2018

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The Holocaust was one of the most traumatic catastrophes ever. Survivors seeking psychotherapeutic treatment today, now in their seventies and older, show the burden of the past becoming less endurable. They may exhibit a depressed or anxious mood as a result of an underlying posttraumatic stress disorder (PTSD). Established psychological treatments for PTSD (e.g., cognitive behaviour therapy, psychodynamic therapies) have been evaluated mainly with young and middle-aged adults, only very few studies have investigated them in old age. No controlled study exists applying those treatments to the special sample of Holocaust survivors. Moreover, there is a need for an age-specific treatment of PTSD and other stress-related mental disorders. A narrative approach including life-review and narrative exposure seems to meet very well the natural need of older people to review their lives and is highly effective. However, most studies on the efficacy of live review therapy (LRT) focus on late-life depression. There is a lack of efficacy studies evaluating the effect of LRT on PTSD symptoms in older individuals that have experienced traumatic events during their lives.
Thus, the main goal of this study is to evaluate the effect of LRT for Holocaust survivors on symptoms of PTSD and related mental health problems (depression, anxiety, prolonged grief), compared to a supportive control group. A secondary goal is to identify features of participants who seem to benefit from the intervention.

Who can participate?
Jewish adults that survived the Holocaust, i.e., were born 1945 or earlier in Europe and having experienced persecution, concentration camp, witnessing torture or death, or having to survive in hiding and/or other traumatic events by the Nazi regime during World War II. They must have one or more of the following mental conditions: Post traumatic-stress disorder (PTSD), complex PTSD, depressive disorder, anxiety disorder, prolonged grief disorder.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group receive life-review therapy (LRT), in addition to attending the social club. Those in the second group attend only the social club (control group). The social club at Amcha centers is a meeting place which answers the need to relate to others. It provides activities like films, lectures, courses in art, music, memory improvement, gymnastics, languages (English, Yiddish), visits to interesting places,

birthday celebrations, discussions of relevant issues, etc. There are no trauma-focussed interventions in the supportive group. LRT treatment consists of 20 sessions over 6 months. It includes six modules: Introduction and motivation; Structured life review; Narrative exposition; Examining stuck points; Recapturing life; Closing of therapy.

What are the possible benefits and risks of participating?
All participants attend the social club that helps them to relate to others and perform pleasant activities. Participants who are randomized to the LRT group will receive an additional psychotherapy program that aims to reduce symptoms of post-traumatic stress, depression, anxiety, and grief. Participants who are randomized to the control group may receive the same psychotherapy program after the end of this study. By taking part in this study there are no risks of physical injury or harm. Elevated levels of stress may be experienced during some psychotherapy sessions, but this may decrease in the same session.

Where is the study run from?
Amcha (Israel)

When is study starting and how long is it expected to run for?
April 2017 to December 2020 (updated 16/03/2021, previously: March 2021.)

Who is funding the study?
1. German Research Foundation (Germany)
2. Claims Conference (USA)

Who are the main contacts?
1. Simon Forstmeier
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2. Elisheva van der Hal-van Raalte
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Contact information

Type(s)
Scientific

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Type(s)
Public

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91029

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG: FO 308/2-1

Study information

Scientific Title
Life Review Therapy for Holocaust Survivors (LRT-HS): A randomised controlled trial

Acronym
LRT-HS

Study objectives
Does the life-review therapy as short-term treatment for Holocaust survivors (in addition to attending the “social club”) reduce the symptoms of PTSD and related mental health problems (depression, anxiety, prolonged grief) more than a supportive control group (attending the “social club” only)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the German Association of Psychology (DGPs),11/01/2016, ref: SF_112015
Ethics committee of the Hebrew University of Jerusalem, School of Social Work, 15/05/2017

Study design
Interventional study design; Randomised controlled trial; one intervention arm (50%), one control arm (50%); single-centred

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://www.bildung.uni-siegen.de/mitarbeiter/forstmeier/projekt1.html

Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD), depression, anxiety disorder, prolonged grief. At least one of these conditions must be present at study intake, either at syndromal (DSM-5 diagnoses) or subsyndromal level.

Interventions
Participants' symptoms of PTSD, depression, anxiety, and grief are assessed and they are randomised at a 1:1 ratio to either:
1. Life-review therapy, in addition to social club (LRT)
2. Supportive control group, i.e., social club only (control)

LRT-HS: includes six modules: Introduction and motivation; Structured life review; Narrative exposition; Examining stuck points; Recapturing life; Closing of therapy. 20 sessions. In addition to attending the social club at Amcha.

Control: "Social club" at Amcha centers; is a meeting place which answers the need to relate to others. It provides activities like films, lectures, courses in art, music, memory improvement, gymnastics, languages (English, Yiddish), visits to interesting places, birthday celebrations, discussions of relevant issues, etc. There are no trauma-focussed interventions in the supportive group.

Randomization: Block randomization, stratified for number of syndromal vs. subsyndromal diagnoses

Outcome variables were assessed at three time points (baseline, end of treatment, follow-up at 6 months after end of treatment).

Intervention Type
Behavioural

Primary outcome measure
Primary endpoints are PTSD and depressive symptoms, assessed at baseline, end of treatment, follow-up at 6 months:
1. PTSD symptoms assessed using PTSD Checklist for DSM-5 (PCL-5)
2. Depressive symptoms assessed using Patient Health Questionnaire (PHQ-9) and Geriatric Depression Scale (GDS)

Secondary outcome measures
Secondary outcome measures are assessed at baseline, end of treatment, follow-up at 6 months:

1. Other symptom measures
- Complex PTSD symptoms: The complex PTSD part of the ICD-11 Trauma Questionnaire
- Anxiety symptoms: The Depression Anxiety Stress Scale-21 (DASS-21)
- Grief symptoms: The ICD-11 Symptom-Diagnostic Test for Prolonged Grief Disorder (PG-ICD-11)

2. Process measures
- Dysfunctional thoughts: The Posttraumatic Cognitions Inventory (PTCI)
- Reminiscence style: The Reminiscence Functions Scale (RFS)
- Positive well-being: The Life Satisfaction Index (LSI)
- Posttraumatic growth: The Posttraumatic Growth Inventory (PTGI)

3.Furthermore, sociodemographic characteristics (age, gender, educational level) and cognitive status (Mini Mental Status Examination, MMSE) are assessed at baseline.

Overall study start date
01/04/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Being a Holocaust survivor, i.e., born 1945 or earlier in Europe and having experienced persecution, concentration camp, witnessing torture or death, or having to survive in hiding and /or other traumatic events by the Nazi regime during World War II.
2. Diagnosis of one or more of the following conditions: PTSD, complex PTSD, depressive disorder (Major, minor depression), anxiety disorder, prolonged grief disorder. Patients with a subsyndromal form of the mentioned disorders can also be admitted to the study.
3. Participants do not receive any psychotherapy treatment during the time of the study (except for LRT in the intervention condition).
4. Participants must have been informed about the study and must have given written informed consent. This includes that he/she is willing to be randomized to one of the study conditions.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50

Total final enrolment

60

Key exclusion criteria
1. Probable dementia (MMSE < 26),
2. Acute psychotic disorder
3. Acute suicidality

Date of first enrolment
01/12/2017

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Israel

Study participating centre
Amcha
23, Hillel Str.
P.O. Box 2930
Jerusalem
Israel
91029

Sponsor information

Organisation
University of Siegen

Sponsor details
Adolf-Reichwein-Str. 2a
Siegen
Germany
57068

Sponsor type
University/education

Website
http://www.uni-siegen.de/

Organisation
Herzog Hospital

Sponsor details
A Teaching Hospital affiliated with the
Medical School of the
Hebrew University of Jerusalem
Givat Shaul St.
Jerusalem
Israel
9103702

Sponsor type
Hospital/treatment centre

Website
http://traumaweb.org/our-team/

Organisation
Amcha

Sponsor details
23, Hillel Str.
P.O. Box 2930
Jerusalem
Israel
91029

Sponsor type
Other

Website
https://www.amcha.org/english

Funder(s)

Funder type
Not defined

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Claims Conference

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study are/will be available upon reasonable request from Simon Forstmeier (simon.forstmeier@uni-siegen.de). Consent from participants was obtained. The data is anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2020	27/04/2020	Yes	No
Results article		08/05/2023	15/06/2023	Yes	No