

A Relaxation Technique enhances Psychological well-being and cellular Immune Competence of elderly people in a nursing home

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| Submission date 13/06/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 27/06/2013 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 28/10/2014 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The aging process involves a decline in immune function that renders elderly people more vulnerable to disease. In residential programs for the aged, it is vital to reduce the risk of disease, to maintain independence, and increase psychological well-being and quality of life. Our goal is to test the effects of a psychological program of geriatric intervention based on the application of a relaxation technique, namely Bensons relaxation technique, on psychological well-being and immune function in elderly people residing in a nursing home.

Who can participate?

Residents of a nursing home (men and women), over 65 years old, without cognitive impairment; not are taking drugs with significant effects on endocrine or immune function; do not have health problems directly related to immune function; and not have suffered an extremely negative life event within the year prior to study participation.

What does the study involve?

The study involved three stages of assessment and an intervention. It was conducted over two weeks. The participants were randomly allocated to a control group (standard care was given by the physician) and treatment group (relaxation technique). The initial assessment was carried out before the first session of relaxation technique training; the other assessments were repeated, at the end of treatment and three months later. Both groups were evaluated at the same time. Finally, clinical and psychological variables were compared in both groups. The control group received the relaxation technique after last assessment (after follow-up).

What are the possible benefits and risks of participating?

It has shown an immediate benefit for those patients who were part of the treatment group. The technique has proven effective in improving psychological well-being of people who practice it.

Participation in this study involved no risk.

Where is the study run from?

The study was carried out in the nursing home Residencia de Tercera Edad Alacant (Juan XXIII). This study was conducted by a multidisciplinary group of psychologists of the Department of Health Psychology of the University of Alicante, in collaboration with physicians of the University Hospital of San Juan of Alicante and Consellería de Bienestar Social (Generalitat Valenciana).

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

The study started in October of 2011, and finished in September of 2012.

Who is funding the study?

Department of Health Psychology, University of Alicante.

Who is the main contact?

Professor Dr. Abilio Reig-Ferrer
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Contact information

Type(s)

Scientific

Contact name

Dr Abilio Reig-Ferrer

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A relaxation technique enhances psychological well-being and cellular immune competence of elderly people in a nursing home: a randomized controlled study

Acronym

RTPIC

Study objectives

The aim of this study was to test the effects of a psychological program of geriatric intervention based on the application of a passive relaxation technique known as Bensons relaxation technique, on psychological well-being and cellular immune competence in elderly people residing in a nursing home. We hypothesized that the Bensons technique would generate positive effects on clinical and psychological well-being.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Residencia de Tercera Edad Alacant (Juan XXIII) of the Consellería de Bienestar Social (Generalitat Valenciana), and Faculty of Health Sciences (University of Alicante). Approval date 05/09/2011

Study design

Randomized controlled study; Psychological intervention

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Elderly, relaxation technique, immune competence, psychological well-being

Interventions

1. Control group: standard care was given by the physician. This group was randomized to wait-list condition.
2. Intervention group: Psychological treatment was given by an expert psychologist. It consisted of an empirical training in the relaxation response technique designed by Benson which we named the tranquilization technique. This relaxation technique consists of engaging in repeated resting periods in which the mind is free from preoccupations and the body is liberated of all tension.

Both groups were assessed before the beginning of the treatment, at the end, and three months later.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Psychological, clinical and immunological measures were collected over the pre-treatment, post-treatment and follow up after the intervention. The following variables were collected:

1. Psychological variables: life satisfaction degree evaluated through the Satisfaction with Life Scale; positive and negative affect assessed with Bradburns Affect Balance Scale; quality of life of the participants by means of Nottingham Health Profile; and a Symptom List related with the Bensons relaxation response.
2. Clinical variables: functional assessment by means of Katz Index of ADL, physical parameters (BMI, blood pressure and heart rate), hematological parameters (red and white blood cells counts, and blood differential, hemoglobin, hematocryte, mean corpuscular volume, platelets, and erythrocyte sedimentation rate) and blood biochemistry measures (Glucose, creatinine, urea, uric acid, total cholesterol, HDL and LDL cholesterol, triglycerids, AST, ALT, GGT, total proteins, and serum albumin).
3. Immunological variables: we recorded the following molecules: CD4, CD8, CD19, CD56, CD71, CD97, CD134, and CD173. At the immune level, our results show significant group differences in various lymphocyte sub populations at the end of treatment.

Secondary outcome measures

At the psychological level, the relaxation technique produced positive effects in that there was a decline in negative affect, degree of psychological distress, and perception of symptomatology with respect to baseline levels at the beginning of the study. Furthermore, the treatment group showed gains in quality of life at the three-month follow-up.

Overall study start date

03/10/2011

Completion date

24/09/2012

Eligibility**Key inclusion criteria**

1. Participants should not to be taking drugs with significant effects on endocrine or immune function (e.g., corticosteroids or antimetabolites)
2. Participants should not to have health problems directly related to immune function (i.e., endocrine diseases, cancer, arthritis, asthma, or infectious diseases)
3. Participants should not have endured an extremely negative life event within the year prior to study participation

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Sample size: 30

Key exclusion criteria

Participants with indications of cognitive impairment

Date of first enrolment

03/10/2011

Date of final enrolment

24/09/2012

Locations

Countries of recruitment

Spain

Study participating centre

Carretera San Vicente del Raspeig

Alicante

Spain

03690

Sponsor information

Organisation

University of Alicante (Spain)

Sponsor details

c/o Abilio Reig-Ferrer

Carretera San Vicente del Raspeig s/n

Alicante

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03690

Sponsor type

University/education

Website

<http://www.ua.es>

ROR

<https://ror.org/05t8bcz72>

Funder(s)

Funder type

University/education

Funder Name

Department of Health Psychology, University of Alicante (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 23/08/2014 | | Yes | No |