

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

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<b>Registration date</b> 27/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2014	<b>Condition category</b> 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  
areig@ua.es

## Contact information

### Type(s)

Scientific

### Contact name

Dr Abilio Reig-Ferrer

### Contact details

Carretera San Vicente del Raspeig  
Alicante  
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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Quality of life

## **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(s)**

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **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)

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

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Department of Health Psychology, University of Alicante (Spain)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	23/08/2014		Yes	No