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A primary care intervention to improve the quality of life of hotel room attendants

Submission date
28/02/2020

Recruitment status
No longer recruiting

Registration date
02/03/2020

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Hotel room attendants are at risk to be exposed to several occupational physical and psychosocial risk factors. The chronic exposure to these risk factors might trigger the development of several chronic disorders, with a negative impact on their quality of life. They have previously reported a higher number of musculoskeletal disorders, chronic pain, higher medication consumption, higher stress perception and poorer health-related quality of life. Some people might define the quality of life according to their wealth or physical health, but also to their family, education, employment or satisfaction with life etc. Such a broad concept is influenced by several factors, both individual (e.g. age, sex, personal preferences etc.) and environmental (lifestyle, working conditions, family and social support etc.), but not all can be modified. Previously the researchers performed a needs assessment of this workforce in the Balearic Islands and several factors were identified as modifiable from primary care setting: smoking, physical activity, dietary habits, chronic pain and stress, among others.
Therefore, the researchers planned a multidimensional complex intervention based on health promotion and prevention for adopting healthy lifestyles, along with empowering the participants to develop coping strategies for stress and chronic pain. This intervention will be carried out by several health professionals in the Balearic Primary Care Health System: registered nurses, physiotherapists and psychologists.
This study has two main aims: to assess the effectiveness of this intervention in order to improve the quality of life of the hotel room attendants and to perform an early evaluation of the implementation process, in order to identify barriers and facilitators for the upkeep of this program in the primary care setting and to ensure its long-term maintenance.

Who can participate?
Any hotel room attendant older than 18 years old, with an assigned general practitioner in the Balearic Islands and who had worked in 2019 summer season.

What does the study involve?
All the participating primary care centers will be assigned by chance to the intervention or control arm. The intervention is scheduled to last 8 weeks, followed by 6 months follow up period. Before the first study visit, all the participants will be contacted by telephone and an appointment with a registered nurse will be scheduled. All participants are required to sign an

informed consent before inclusion.
The participants assigned to the intervention group will be participating in one individual session (visit 1) where nurse professionals will collect information about their diet habits, smoking status, quality of life and stress among others. Those participants who require changes on their lifestyle will receive personalized recommendations according to their stage of change. After this initial visit, the participants will be visited by a physiotherapist (visit 2), who will collect information about their physical activity and pain (duration, intensity and location) among others. All the hotel room attendants will receive an individualized therapeutic exercise program, personalized according to their preferences and pain. Those participants willing to carry out community activities will be offered five/six aquatic exercise sessions in public communal pools. A total of 5 group visits of 120-150 minutes each, will be scheduled, and will be performed by psychologists, nurses and physiotherapists. These group sessions will be focused according to the health professional conducting it: stress and pain coping strategies based on pain neuroscience education will be offered, along with raising attitude, intention and motivation to change and to adopt healthy lifestyle, among other factors that might improve the quality of life. One individual visit performed by nurse professionals will be carry out when group sessions ends (visit 8), where reinforcement and empowerment for change will be highlighted. Six months after the intervention ends, one final individual visit will be performed (visit 9, final visit).
For the control group, during baseline visit (visit 1) the nurses will collect information related with the quality of life, diet habits, smoking status, psychical activity, chronic pain and stress, among others. At the end of this visit usual care recommendation on health promotion and healthy lifestyle will be delivered. All the participants from the control group will be again visited six months after (visit 2, final visit).

What are the possible benefits and risks of participating?
This study would allow the researchers to understand if a multidimensional intervention conducted in primary health care is effective for the improvement of the quality of life of the hotel room attendants. Primary care setting is the convenient site for health promotion and prevention, therefore if effective and cost-effective, this intervention can be implemented as a health promotion program for this workforce. Along healthy lifestyle adoption, the researchers are also expecting chronic pain reduction and lesser stress perception. No major risks neither major adverse effects are expected to happen during study period.

Where is the study run from?
Balearic Public Health System Service: Primary Care Management of Majorca, Ibiza and Formentera, Menorca; Spain.

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

Who is funding the study?
This study is funded by the Balearic Government, Agència d´Estratègia Turística de les Illes Balears, Sustainable Tourism Tax Grant.

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Additional identifiers

Protocol serial number
v.10

Study information

Scientific Title
Effectiveness of a multidimensional complex primary care-based intervention to improve the quality of life of hotel room attendants: a cluster hybrid type I randomized controlled trial.

Study objectives
1. A multidimensional complex intervention performed in primary care based on health promotion and empowerment of the hotel room attendants will:
1.1. Improve their quality of life
1.2. Increase the proportion of participants with a clinically meaningful difference on their general health dimension of the SF36 questionnaire
1.3. Be cost-effective
2. A higher proportion of participants from the intervention group will improve their attitude, intention, self efficacy, motivation and acting planning for change and will:
2.1. Adopt healthy lifestyles (quit smoking, improve their adherence to the Mediterranean diet and their physical activity).
2.2. Report a reduction of chronic pain and perceived stress
2.3. Improve their global satisfaction with life, wellbeing and self-rated health perception, less use of health systems resources, less analgesics and psychotropic consumption, and fewer sick leaves days.
3. The intervention will be feasible and appropriate for the primary care setting, and easy to accept and adopt for both participants and health care professionals

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 05/12/2019, Research Ethics Committee of the Balearic Islands (Consejería de Salud y Consumo, Dirección General de Investigación en Salud, Formación y Acreditación, Comité de Ética de la Investigación de las Islas Baleares (CEI-IB), Calle de Jesús, 38 A, 07010 Palma (Islas Baleares); +34 971 177 378; ceic_ib@caib.es)

Primary study design
Interventional

Study design
Cluster randomized clinical trial hybrid type I (effectiveness – implementation)

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Health-related quality of life

Interventions
An intervention mapping process was followed for designing the intervention. The ecological model I-Change was used as a logic model of change and the following determinants were established in order to achieve performance objectives: cognizance, knowledge, risk perception, perceived cues, attitude, social support, self-efficacy, intention and action planning. The intervention will last 8 weeks, will be evaluated at 8 months since inclusion and will comprise individual, group and community components. Registered nurses, physiotherapists and psychologists will carry out the sessions.

All the participants will be contacted by phone and the invited participants agreeing to participate, will be scheduled an appointment with the nurse professional, if signing informed consent. This inclusion visit (visit 1, week 1) will last 75 minutes and baseline information will be gathered, along with delivering tailored and individualized recommendations on diet and smoking. Visit 2 (week 2), also 75 minutes long will be performed by a physiotherapist, who will collect data on pain and physical activity and will provide tailored and individualized recommendations for physical activity and coping strategies for chronic pain based on pain neuroscience education. Aquatic exercises at public pools will be offered to all willing participants. The third visit (visit 3, week 3) will be a group visit, 120 minutes long, which a psychologist will work stress aspects throughout individual and group reflections and role playing. Other group visits: visit 4 (week 4) and 6 (week 6) of 150 minutes long, the nurse will carry out the follow-up on the dietary behavioral changes achieved and reinforcing them throughout verbal persuasion and feedback, identifying the barriers and facilitators for accomplished changes, followed by 60 minutes of walking (¨healthy route¨) neighboring the community of the health care center. Visit 5 (week 5) and 7 (week 7) will be performed by physiotherapists and psychologists, in which progress on physical activity and adherence will be discussed and reinforced throughout verbal persuasion and feedback; afterwards relaxation techniques will be performed for 60 minutes. The following 90 minutes the psychologists will provide coping strategies for stress management and emotional regulation. An interim evaluation (visit 8, week 8) will be performed during the eighth visit (individual) performed by nurses. Finally, six months after the intervention ends, the participants will attend one last individual visit with the nurse, in which the study final evaluation will be performed.

Control group will attend two individual sessions with the nurse, wherein data collection and usual care recommendations on healthy lifestyle will be delivered.

Intervention Type
Behavioural

Primary outcome(s)
1. Health-related quality of life, measured by the Spanish version of SF 36 questionnaire: inclusion visit (week1), visit 8 (week 8) and visit 9 (6 months after the intervention ends)
2. Early implementation process evaluation in terms of appropriateness, acceptability, adoption and feasibility measured using mixed methods approach: week 3, 4, 6 and 7 (measured by single questions with 10-point Likert answer option for the quantitative data) and 2 focus groups with participants and health professionals within 3 months after the study finishes

Key secondary outcome(s)
1. Economic evaluation in terms of cost and utilities: SF6D questionnaire - at the end of the study
All the secondary objectives described below will be measured at inclusion visit (week 1), visit 8 (week 8) and visit 9 (6 months after the intervention ends):
2. Motivation for change: we will use 15 items Motivation Questionnaire to Adopt a Healthy Lifestyle (treatment self-regulation questionnaire Spanish adaptation)
3. Assessment of stage of change (attitude, intention, planning) for each lifestyle: tobacco, diet, physical activity, using one single question for each stage
4. Self-efficacy measured using a 10 items General Self-efficacy Scale
5. Smoking status measured by self-report
6. Adherence to the Mediterranean diet: measured by 14 items Predimed questionnaire
7. Physical activity: using 7 items IPAQ questionnaire
8. Pain: measured by Visual Analogic Scale (VAS)
9. Self-perceived health status: using Spanish Single-item Self-perceived health status
10. Well-being: using 5-item World Health Organization Well-Being Index
11. Perceived stress: is being measured using 4 items Perceived Stress Scale (PSS-4)
12. Global life satisfaction: using a Spanish Single-item Life Satisfaction Scale
13. Healthcare resource utilization, analgesic and psychotropic consumption, and sick-leaves number and mean days: electronical medical records

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Hotel room attendants older than 18 years who worked in the last summer season and with health coverage in the Balearic Primary Care Health System

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant women
2. Not speaking nor understanding Spanish or Catalan
3. Being on sick leave
4. Included in another clinical trial
5. Psychiatric disorders
6. Any positive answer on the Physical Activity Readiness Questionnaire (Par-Q)

Date of first enrolment
09/03/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Spain

Study participating centre
Gerencia de Atención Primaria de Mallorca
Calle Escuela Graduada, número 3
Mallorca
Spain
07002

Study participating centre
Gerencia del Área de Salud de Menorca
Ronda de Malbúger, 1
Mahón
Spain
07703

Study participating centre
Gerencia del Área de Salud de Ibiza y Formentera
C/ de la Corona s/n
Eivissa

Spain
07800

Sponsor information

Organisation
Agència d´Estratègia Turística de les Illes Balears

Funder(s)

Funder type
Government

Funder Name
Agència d´Estratègia Turística de les Illes Balears

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary
Stored in repository