ISRCTN13415993 https://doi.org/10.1186/ISRCTN13415993

The TTCYB study protocol: a tailored print message intervention to improve cardiovascular patients' lifestyles

Submission date
23/01/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Education about lifestyle change is a priority for patients' health and communication interventions offer promising strategies for promoting healthier behaviours. One of the most challenging issues in health promotion research is the creation and delivery of messages that are relevant, interesting, informative, and persuasive. Tailored print communication based on the needs, preferences and personal characteristics of the target is an example of a communication approach that has attempted to address these characteristics and has been widely applied in the area of health promotion. Tailored messages are thought to facilitate changes in several behaviours by providing personally relevant information and feedback.
To date, little is known about the efficacy and the long-term outcomes of tailored versus non-tailored communication interventions, especially among cardiovascular patients.
The TTCYB is a randomized controlled intervention that uses tailored health print educational material to improve healthy lifestyle behaviours in patients affected by acute coronary syndrome (ACS) or essential hypertension. It is a pragmatic intervention that primes the patient to self-manage by making relevant changes in four behaviours: diet, physical activity, alcohol intake and smoking.
The specific aims of the study will be:
1. To determine whether tailored materials are perceived as more useful, understandable, and complete compared to non-tailored ones;
2. To understand whether the TTCYB intervention is effective in promoting changes in diet, alcohol use, physical activity, and smoking behaviour among patients with CVDs;
3. To explore the effects of the TTCYB intervention on secondary endpoints, including body mass index and systolic and diastolic blood pressure;
4. To evaluate socio-demographics and psychological factors which could moderate the effectiveness of the intervention.

Who can participate?
Patients affected by acute coronary syndrome (ACS) or essential hypertension.

What does the study involve?
At baseline and the 6-month follow up, patients will complete a series of self-report questionnaires evaluating lifestyle behaviour socio-demographic and psychological characteristics; at the 12-month follow up, patients will have a telephone interview that will assess lifestyle habits. After the baseline measurement, patients will be randomized into one of three groups: 1) the tailored group (T), which will receive tailored health brochures 2) the “non-tailored” group (NT), which will receive non-tailored health brochures; 3) the usual care group (UC), which will receive no print information materials. Participants will be assigned to one of the three study groups using a stratified randomization process characterized by unpredictability of assignments. Within ten working days of completing the questionnaire, both at baseline and the 6-month follow-up, the T and NT groups will be mailed printed health materials while patients in the UC group will receive no materials. Patients in the T and NT group will be then contacted by phone for an interview to measure their judgment of the material. At the 12-month follow up, all patients will have a telephone interview that will assess their lifestyle in terms of diet behaviour, physical activity, alcohol intake and smoking behaviour.

What are the possible benefits and risks of participating?
Participants in T and NT groups receive health material about their disease and therefore could appear as more informed about their health status. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
The TTCYB study runs from the University of Milan-Bicocca and takes place in different hospitals around the area of Milan.

When is the study starting and how long is it expected to run for?
May 2010 to December 2020.

Who is funding the study?
Italian Ministry of Instruction, University and Research–FIRB “Futuro in ricerca” [grant number RBFR08YVUL].

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The “Time to Change Your Behaviour” (TTCYB) study protocol: a theory-based, tailored print message intervention to improve compliance with the self-care regimen recommended for patients with cardiovascular diseases

Acronym
TTCYB

Study objectives
Tailored health print educational material to improve healthy lifestyle behaviours in patients affected by acute coronary syndrome (ACS) or essential hypertension will be perceived as more useful, understandable, and complete compared to non-tailored one;
tailored material will be more effective in promoting changes in diet, alcohol use, physical activity, and smoking behaviour than non tailored material.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University of Milan-Bicocca, 17/09/2010, ref. 0021536.

Study design
A three-arm parallel-group multi-site randomized intervention trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Acute coronary syndrome and essential hypertension

Interventions
At baseline and the 6-month follow up, patients will complete a series of self-report questionnaires evaluating lifestyle behaviour socio-demographic and psychological characteristics; at the 12-month follow up, patients will have a telephone interview that will assess lifestyle habits.

After the baseline measurement, patients will be randomized into one of three groups:
1. The tailored group (T), which will receive tailored health brochures
2. The “non-tailored” group (NT), which will receive non-tailored health brochures;
3. The usual care group (UC), which will receive no print information materials.

Participants will be assigned to one of the three study groups using a stratified randomization process characterized by unpredictability of assignments. Within ten working days of completing the questionnaire, both at baseline and the 6-month follow-up, the T and NT groups will be mailed printed health materials while patients in the UC group will receive no materials. Patients in the T and NT group will be then contacted by phone for an interview to measure their judgment of the material. At the 12-month follow up, all patients will have a telephone interview that will assess their lifestyle in terms of diet behaviour, physical activity, alcohol intake and smoking behaviour.

Intervention Type
Other

Primary outcome(s)
1. Change in lifestyle habits will be measured using self-report questionnaires at baseline and at 6-month follow up while at 12-month follow up data will be collected by a telephone interview.
1.1. Change in Diet will be measured using a modified version of the Mediterranean Diet Scale (MDS, Trichopoulou, Costacou, Bamia, & Trichopoulos, 2003).
1.2. Physical ecercise will be measured using RAPA-1 and RAPA-2 of Rapid Assestment of Physical Activity (RAPA, Topolski et al., 2006).
1.3. In order to collect data about alcohol use subjects will have to indicate the consumption of wine/beer (never; up to 2 glasses per day; up to 4 glasses per day; more than 4 glasses per day) and of super alcoholic drinks (never; occasionally just 1 glass; habitually 1 glass; habitually more than 1 glass) following a scale used by Giovannucci et al. (1991).
1.4. Subject will have to indicate if they are smokers or not.
2. Patients’ judgments about health material will be measured using structured phone interview questions (with a 5 Likert scale) at baseline and at 6-month follow up (10 days after material reception). Patients will have to assess their use of the health material received in terms of usefulness, clarity, personalization, efficacy in modifying lifestyle.

Key secondary outcome(s))
Current secondary outcome measures as of 29/05/2019:
1. Changes in physiological parameters will be measured using values of BMI, waist circumference, blood pressure, diabetes mellitus (presence or not) collected by a physician at baseline and at the two follow-ups.
2. Medical adherence will be measured using a modified version (new items added) of the Self-reported Measure of Medication Adherence (Morisky, Green & Levine, 1986) at baseline and at the two follow-ups.

Previous secondary outcome measures:
1. Changes in physiological parameters will be measured using values of BMI, waist circumference, blood pressure, diabetes mellitus (presence or not) collected by a physician at baseline and at the two follow-ups.
2. Medical adherence will be measured using the 8-items Morisky Medication Adherence Scale (MMAS, Morisky, Ang, KrouselWood, & Ward, 2008) at baseline and at the two follow-ups.

Completion date

31/12/2020

Eligibility

Key inclusion criteria
1.18 years of age or older.
2. Diagnosis of essential arterial hypertension (SBP>=140 mmHg and/or DBP>=90 mmHg, evaluated in the standard way or by 24-hour mean arterial pressure value [MAP] monitoring) or ACS.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to complete the study measures and interventions in Italian.
2. Affected by other serious diseases (such as cancer) or psychiatric disorders.

Date of first enrolment
01/02/2011

Date of final enrolment
21/12/2016

Locations

Countries of recruitment
Italy

Study participating centre
Centro per Diagnosi e Cura dell'Ipertensione Arteriosa dell’Azienda Ospedaliera Treviglio-Caravaggio di Treviglio
Treviglio, BG
Italy
24047

Study participating centre
UOSD Cardiologia Riabilitativa- IRCCS INRCA POR di Casatenovo
Casatenovo, LC
Italy
23880

Study participating centre
Istituto Auxologico Italiano di Meda
Meda, MB
Italy
20821

Sponsor information

Organisation
University of Milano Bicocca

ROR
https://ror.org/01ynf4891

Funder(s)

Funder type
Government

Funder Name
Italian Ministry of Instruction, University and Research–FIRB “Futuro in ricerca” [grant number RBFR08YVUL].

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/04/2020	18/10/2022	Yes	No
Interim results article	preliminarily effectiveness	05/03/2024	06/03/2024	Yes	No