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A novel approach to clinical practice by using a shared decision-making model to target cardiovascular risk: The YANKEES study

Submission date
21/05/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
15/07/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The overall goal of the project is to decrease the cardiovascular risk among the patients of South Bronx population by utilizing a SDM intervention model to encourage health dietary choices, advocate exercise, educate, prompting patient decisions and directing self-efficacy to the healthier choices, to accomplish weight reduction (change in weight) and blood-pressure control (decrease and maintenance of healthy blood pressure).
Shared Decision Making combines subject preferences with evidence-based medicine in a collaborative conversation to help the person determine their optimal treatment approach. In SDM, both parties share information: the clinician offers options and describes their risks and benefits, and the patient expresses his or her preferences and values. Each participant is thus armed with a better understanding of the relevant factors and shares responsibility in the decision about how to proceed. This is a process of open communication or mutually acceptable decision. In this project, the research staff will offer to participant personalized information about treatment and prevention options and their associated risks and benefits. The participant then should communicate to the staff his or her values, preferences and concerns related to these variables. The goal is to arrive at a joint decision regarding the best strategy. Patients will be informed, more likely to comply with the plan and more likely to be satisfied with their outcome.

Who can participate?
Clinic patients aged over 18, who have had at least two appointments and follow-ups can take part.

What does the study involve?
This study will engage patients in implementing a Shared Decision-Making (SDM) model to enhance clinician and patient communication to achieve an informed decision on evidence-based practices. The SDM group will be allocated to Weight Management (BMI reduction) or Blood-Pressure Control (Systolic Reduction). SDM group will be compared to a control group which will be the Usual Decision Making (UDM), where individuals will utilize their own resourcefulness to achieve similar goals of weight and blood-pressure control.

The duration of the study is one-year and at Baseline (initial interaction), 3-months, 6-months, 9-months and 12-months subjects will be evaluated via outcome measurements listed.

What are the possible benefits and risks of participating?
Possible Benefits:
Benefits of SDM intervention are the interpersonal challenge of the patient to Think-Plan-Do. Activities that allow the mastery of self to achieve a healthier lifestyle practice that can be managed over time to reduce weight and manage blood pressure.
We cannot and do not guarantee that you will receive any other benefits from this study. However, we hope that the study populations of the participating health-center's vicinity may benefit from the knowledge and information subjects in the SDM arm of the study gained during the intervention.
Some participants may:
· Change eating and exercise habits and may experience improvements in their general health as a result.
· Lose weight and may experience benefits associated with this weight loss.
· Participants will strengthen their medication/physician compliance.
· Improve their sleep hygiene.
· May cease or decrease their alcohol consumption and/or smoking.
The participants that experience these benefits will ultimately lead to an improvement in the participant's health and behavior.

Possible Risks:
All collected information will be de-identified and maintained confidential in a secure network storage location, meeting or exceeding corporate requirements of with in HIPAA secure facility. Some of the questions asked may be too personal and could cause embarrassment or stress the participant or enhance a sense of anxiety. Participants may skip questions that they do not wish to answer

Where is the study run from?
Lincoln Center for Clinical and Community Research, NY, USA.

When is the study starting and how long is it expected to run for?
June 2019 to June 2020

Who is funding the study?
New York State Department of Health, USA

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
18-020

Study information

Scientific Title
A novel approach to clinical practice by using a shared decision-making model to target cardiovascular risk: The YANKEES (Your demographics, Adherence, Nutrition, Knowledge, Environment, E-EtOH [alcohol], Smoking, Sleep-quality) study

Acronym
YANKEES

Study objectives

In our attempt to help reduce cardiovascular disease risk, the shared decision making (SDM) cohort will demonstrate superiority over usual decision making (UDM) cohort, by decreasing body mass index (BMI) in obese individuals by two units and decreasing systolic blood pressure (SBP) in hypertensive participants by at least 10 mmHg.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/08/2018, Lincoln Medical and Mental Health Center IRB (234 East 149th street, Bronx, NY 1045; 718-579-5339; lincolnirb@nychhc.org), ref: 18-020.

Study design
Prospective randomized controlled study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obesity, Hypertension, Cardiovascular Disease

Interventions
Our project has two arms, the Shared Decisions Making (SDM) and Usual Decision Making (UDM).

Shared Decision Making combines subject preferences with evidence-based medicine in a collaborative conversation to help the person determine their optimal treatment approach. In SDM, both parties share information: the clinician offers options and describes their risks and benefits, and the patient expresses his or her preferences and values. Each participant is thus armed with a better understanding of the relevant factors and shares responsibility in the decision about how to proceed. This is a process of open communication or mutually acceptable decision. In this project the research staff will offer to participant personalized information about treatment and prevention options and their associated risks and benefits. The participant then should communicate to the staff his or her values, preferences and concerns related to these variables. The goal is to arrive at a joint decision regarding the best strategy. Patients will be informed, more likely to comply with the plan and more likely to be satisfied with their outcome.

The Usual Decision Making (UDM) intervention or traditional biomedical care system will be the control group in this study.

600 participants from the ambulatory clinic at the Lincoln Hospital will be recruited and randomized into 2 groups, the Shared Decision Making (SDM) and Usual Decision Making (UDM) to test the effectiveness of interventions using SDM in changing participants health habits, compared to usual education and decision making (UDM). The overall goal of this study is to decrease the cardiovascular risk among the ambulatory clinic patients by utilizing a SDM intervention model to encourage health dietary choices, advocate exercise, educate, prompting

patient decisions and directing self-efficacy to the healthier choices, to accomplish weight reduction (change in weight) and blood-pressure control (decrease and maintenance of healthy blood pressure).

The interventions will take place in the form of Long (40 mins, ~100 Questions) and Brief (5 mins, ~5 Questions) sessions. The subject participation will take place over a 6 month time frame with a long-term follow-up at 12 months. Key interventions and follow-up will take place at Initial visit (recruitment day), with 3-, 6-, 9- and 12-month follow-ups.

The Research Team is made up of Clinical Doctors and Medical Students that have been trained in Shared Decision Making (SDM) guidelines and patient engagement strategies to implement SDM model.

Randomly assignment of subjects to treatment (SDM) and control (UDM) groups (repeated only once). Total participants 600; SDM=300 and UDM=300.

Data for each time point will be gathered via paper Case Report Forms (CRFs) and entered into a data capture system on institutes HIPAA protected Intranet data-storage server (only accessed by designated Research Team Members). After data-entry and quality review is performed, de-identified data will be extracted via Microsoft Access into a Microsoft-Excel sheet. And data files will be uploaded on to statistical software, STATA SE version 14, for analysis.

Intervention Type
Behavioural

Primary outcome(s)
At baseline, 3-months, 6-months, 9-months, 12-months:
1. Salt intake measured using Salt questioner (adapted from WHO STEPwise approach to chronic disease risk factor surveillance of Dietary salt module)
2. Diet measured using Rate Your Plate (adapted from 2000 Brown University Center for Primary Care and Prevention, Pawtucket, RI 02860)
3. Nutrition measured using Automated Self-Administered 24-Hour (ASA-24Hrs; 24-Hour Dietary Intake Caloric Assessment from NIH Automated Self-Administered 24-Hour Dietary Assessment Tool)
4. Physical activity measured using IPAQ 7-days tool

Key secondary outcome(s))
1. Medical Knowledge measured using Questioner on High-Blood Pressure (1) and Obesity (2) to gauge knowledge of the disease awareness and disease process at baseline, 6-months, 12-months
2. Mental and emotional health measured using PHQ-9 at baseline, 6-months, 12-months.
3. Commitment to outcome measured using stage of change scale at baseline, 3-months, 6-months, 9-months, 12-months
4. Self-efficacy measured using the General Self-Efficacy Scale (GSES) at baseline, 3-months, 6-months, 9-months, 12-months
5. Environmental factors measured using a home and work environment questionnaire at baseline, 6-months, 12-months
6. Medication Adherence measured using a modified medication adherence assessment adapted from Morisky Medication Adherence Scale at baseline, 6-months, 12-months
7. Alcohol use measured using AUDIT questionnaire at baseline, 6-months, 12-months
8. Smoking behavior measured using smoking questions at baseline, 6-months, 12-months

9. Sleep measured using a modified version of the Pittsburgh Sleep Quality Index (PSQI) at baseline, 6-months, 12-months
10. Major Stressful Life Events measured using a novel questionnaire at baseline, 6-months, 12-months
11. Social Support and Relationship measured using a novel questionnaire at baseline, 6-months, 12-months

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Ambulatory clinic patients that have an established record with a history of two appointments and follow-ups
2. Age 18 years and above
3. Hypertension, medical diagnosis with no more than three anti-hypertensive medications
4. Medical diagnosis of Diabetes Mellitus with hemoglobin A1c less than or equal to 8.0%
5. Calculated Body Mass Index between 25 kg/m2 and 40 kg/m2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to provide informed consent in either English or Spanish for any reason, including cognitive impairment, psychiatric illness, drug or alcohol intoxication
2. Pregnant or are planning to become pregnant within the year
3. Participating in other trials, e.g. weight loss study
4. Prior history or present medical condition and/or surgical procedure related to the primary gastrointestinal tracts and/or accessory digestive organs affecting the transit or absorption of ingested nutrients, including but not limited to bariatric, pancreatic disease and multiple bowel surgeries
5. Severe comorbid diseases that can lead to unintentional weight change including cancer, HIV /AIDS, autoimmune disease, including and not limited to inflammatory bowel disease, in addition to chronic kidney disease, chronic liver disease and chronic heart disease
6. Severe disease, a terminal illness, be incapacitated (including stroke, myocardial infarction, coronary artery disease) with an expected limited life-span of less than a year
7. Living in an institutional setting (including nursing home, prison or group home)

8. Lab value abnormalities that preclude from participation in study interventions (i.e. significant anemia; derangement in electrolytes; elevation in liver function test; etc.) determined by the Investigator
9. Abnormalities in electrocardiogram studies, unless reviewed and cleared by a physician

Date of first enrolment
01/06/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
United States of America

Study participating centre
NYC Health + Hospitals/Lincoln
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Sponsor information

Organisation
New York State Department of Health

ROR
https://ror.org/04hf5kq57

Funder(s)

Funder type
Government

Funder Name
New York State Department of Health

Alternative Name(s)

Department of Health, NYS Department of Health, NY State Department of Health, New York State Health Department, Departamento de Salud del Estado de Nueva York, Département de la santé de l'État de New York, Dipartimento della Salute dello Stato di New York, Departamencie Zdrowia Stanu Nowy Jork, NYSDOH, NYSDOH NY

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United States of America

Results and Publications

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

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