

Evaluation of an educational online intervention aiming to improve primary care physicians' awareness of addressing social determinants of health in clinical care in Saudi Arabia

Submission date 18/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2021	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Primary care services provide the first point of contact in the healthcare system. Social determinants of health are conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. There is an increasing body of literature on measures that primary care physicians (PCPs) may use to incorporate social determinants of health (SDH) into their routine primary care practice. However, there is a gap in evidence regarding changing physician behavior to take action on SDH. Our study aims to evaluate the feasibility and acceptability of a cluster randomized trial evaluating the effectiveness of an educational online intervention in improving primary care physicians' knowledge, empathy and behavioral intention to adopt a social determinant of health approach in clinical care.

Who can participate?

Men and women both Saudi and non-Saudi primary health care physicians (who are either Family Medicine Physicians (FM) or General Practitioners (GP) who are clinically active, serving patients within Riyadh and registered at the Saudi Committee for Health Specialties.

What does the study involve?

The participants will take part in a questionnaire survey, made up of 48 items, based on validated measures and scales. The participants will receive the questionnaire at the beginning of the first quarter of the year and will be given three months to complete it (baseline). Reminder emails will be sent. Seven months later the same participants will be divided and receive either the original questionnaire or the questionnaire that includes the educational intervention, which is simplified four-step tool and physician aid that encourages them to ask about common social determinants of health, and to refer them to the local support organizations and resources available.

What are the possible benefits and risks of participating?

We expect the study to bring a fresh perspective on assessing the impact of interventions addressing social determinants of health in clinical care. There are no risks in participating as this is a text message-based self-completion questionnaire, and the respondent has the freedom to agree or disagree from the start on whether they wish to partake in this survey or not.

Where is the study run from?

King Khalid University Hospital and single-physician primary care practices run by the Ministry of Health (MoH) (Saudi Arabia).

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

May 2016 to March 2021.

Who is funding the study?

The Saudi cultural bureau in Ottawa, Canada.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

R2019-2020

Study information

Scientific Title

A protocol for a pilot cluster randomized controlled trial for the evaluation of an educational online intervention aiming to improve primary care physicians' awareness of addressing social determinants of health in clinical care in Saudi Arabia

Study objectives

In a population of Saudi primary health care physicians, can a translated and locally adapted educational online intervention improve their knowledge, empathy and behavioral intention to adopt a social determinant of health approach in clinical care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/05/2016, King Saud University College of Medicine Institutional Review Board (PO Box 7805, Riyadh 11472, K.S.A.; +966 114691531; aleyadhy@ksu.edu.sa), ref: 18/0405/IRB

Study design

Parallel group cluster randomized controlled trial, with workplace as the unit (cluster) considered in the allocation to the study arms (online education versus no online educational)

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Social determinant of health approach to clinical care

Interventions

Educational online intervention: A one-page Riyadh-specific insert within the two-page leaflet of the locally adapted Arabic-translation of the CLEAR toolkit will reflect the culture of practice and local terminology in Saudi Arabia, and include the appropriate list of local referral agencies and organizations. This tool, which is a simplified, easy to navigate four-step approach (treat, ask, refer and advocate), will function to guide primary health care physicians in Riyadh to first treat any underlying medical illnesses and symptoms, second how to ask about nine common social determinants of health and address their patients' social determinants of health and refer them to the corresponding support organizations and resources available. Finally, the tool gives tips on how physicians can advocate for more supportive environments and get involved with leaders and local community members.

Data collection tool: An emailed self-administered questionnaire will include four main components with a total of 50 items, mostly based on validated measures and scales found in the literature for our chosen outcome measures.

Data collection: Personalized emails to the eligible participants will be sent out after the researchers obtain an encrypted web-link from the independent statistician to be inserted in the respective email. This web-link will refer to either the educational intervention and questionnaires for either the control or intervention arm. The control group will receive questionnaires at baseline (time of response after randomization) and at 1-month follow up. The group randomized to the intervention will receive baseline questionnaires and then at 1-month follow up will receive the web link that includes both the educational intervention and questionnaires. The primary contrast will be between intervention and control centers at the second timepoint.

Intervention Type

Behavioural

Primary outcome measure

Knowledge of primary care provision measured using a novel research survey at baseline and one year

Secondary outcome measures

Measured at baseline and one year:

1. Empathy is measured by using The Jefferson Empathy Scale for health physicians
2. Intention to change is measured by using Theory of Planned Behavior Questionnaire

Overall study start date

10/05/2016

Completion date

15/03/2021

Eligibility

Key inclusion criteria

1. Saudi and non-Saudi trained primary health care physicians of both sexes
2. Either Family Medicine Physicians (FM) or General Practitioners (GP)
3. Clinically active, serving patients within Riyadh and registered at the Saudi Committee for Health Specialties

Primary health care centers excluded from this study are those located outside Riyadh city where local support organizations and community referrals are not within reach for patients in need.

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

Of 435 primary health care centers in and around the greater Riyadh area, 96 centers are in two large health care facilities. King Khalid University Hospital (KKUH) has 48 clinics, with the number of physicians per clinic varying from 3 to 10. The pilot trial includes all physicians in 48 clinics, with no subsampling (n=100). This covers a significant proportion of Riyadh, serving a wide variety of patients including those with greater marginalization and lower socio-economic status.

Total final enrolment

86

Key exclusion criteria

Non clinically active physicians and training residents with less than 3 years of experience with patients

Date of first enrolment

18/05/2018

Date of final enrolment

15/08/2019

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre**King Khaled University Hospital**

Department of Family and Community Medicine

Primary Health Care Clinics

PO Box 7805

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Sponsor information**Organisation**

McGill University Health Centre

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.mcgill.ca/familymed/>

ROR

<https://ror.org/04cpxjv19>

Funder(s)

Funder type

Government

Funder Name

Saudi Arabia Cultural Bureau in Ottawa

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal e.g. PLoS One.

The researchers expect the study to bring a fresh perspective on assessing the impact of interventions addressing social determinants of health in clinical care. The results will be of interest to primary health care physicians, social workers, health educators, health policymakers, as well as knowledge translation researchers and behavioral scientists interested in the determinants of behavior and behavior change. The pilot cluster randomized controlled trial of the educational value of the Saudi version of the CLEAR toolkit seeks to test the feasibility and acceptability of this evaluative approach if conducted later at a larger scale. It will also generate evidence on direction of impact, variances, covariates and intra-cluster correlation coefficients to increased physician knowledge, empathy, and behavioral intention to adopt a social determinants approach to clinical care among the intervention group as compared to the control group.

Intention to publish date

15/02/2021

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