Heart Health Without a Doctor

SPICES · NOTTINGHAM TRENT UNIVERSITY

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EU Horizon 2020 R&D funded 'SPICES' Scaling up Packages of Interventions for the prevention of Cardiovascular disease in selected European and sub-Saharan countries (an implementation research project) Grant agreement no:733356 Non-communicable diseases and the challenge of healthy ageing

Background

The economic and social consequences of CVD concern governments and health systems across the globe. These consequences threaten to undermine quality of life gains in high and low income settings alike. Most commonly, the burden of primary prevention and the treatment of non-communicable diseases is with Primary Care, raising significant capacity and sustainability challenges.

Aims

The aims of the 'SPICES' Nottingham study are to investigate efficacy and scalability of evidence based primary CVD prevention outside of formal healthcare settings using non-clinical and to compare results with those of our 5 other global study sites with reference to differing income levels and healthcare systems.

Methods

Using a mixed-methods Implementation Science approach, the study has identified best-evidenced intervention themes and components from systematic literature and guideline reviews. Participants are recruited through a community engagement methodology and profiled using the non-clinical INTERHEART CVD risk prediction instrument, repeated six-monthly over a two year period. Participants at medium risk of CVD morbidity are randomised into Intervention and Control groups. Participants in the intervention groups are offered a series of behaviour change support workshops over twelve months which incorporate the best-evidenced components identified through our literature and guideline reviews.

Efficacy is measured through quantitative analysis of change in predicted risk scores over two years. Implementation is measured through qualitative analysis of factors which include barriers and facilitators of change, reach, adoption, fidelity, maintenance. The Social-Ecological model of health provides the framework for qualitative analysis.

Results

Fieldwork began in April 2019 and will be complete in March 2021. In Nottingham over 1000 participants are expected to take part in the baseline survey with at least two hundred expected to be invited into the intervention trials.

Month	Quantitative	Qualitative	Step 1	Step 2	Step 3
0	INTERHEART, WHOQOL n=600		Baseline Survey		
1	IPAQ DASH-Q n=67	Problem Solving (Barriers: Material/Psychological/Social/Environmental)	Medium Risk randomised into Intervention arm n=67	Control Arm	Control Arm
2	IPAQ, DASH-Q	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
3	IPAQ, DASH-Q	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
4	IPAQ, DASH-Q n=134 (cumulative)			Medium Risk randomised into Intervention arm n=67	
5	IPAQ, DASH-Q				
6	IPAQ, DASH-Q	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
6	INTERHEART, WHOQOL n=600				
7	IPAQ, DASH-Q n=200 (cumulative)				Medium Risk randomised into Intervention arm n=66
8	IPAQ, DASH-Q				
9	IPAQ, DASH-Q				
12	INTERHEART, WHOQOL n=600	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
18	INTERHEART, WHOQOL n=600	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
24	INTERHEART, WHOQOL n=600	Problem Solving (Barriers: Material/Psychological/Social/Environmental)			
27					
			24 months 5 baseline measurements 9 intervention measurements	24 months 5 baseline measurements 9 intervention measurements	21 months 4 baseline measurements 8 intervention measurements

Study Sample Size

The sample size calculation for the quantitative study used statistical modelling for a stepped wedge design, randomising community centres over time with the InterHEART score as the outcome (90% power for 5% significance, small effect size (Cohen's D)=0.25, intracluster correlation coefficient of 0.05, control clusters crossing to intervention in 4 steps, participant autocorrelation=0.7 and cluster autocorrelation=0.9), which requires a total of at least 144 persons. This needs approximately 200-300 people across the two sites as we expect a high level of attrition (as much as 50%). At least 1500 community members will need to be screened to achieve this recruitment.

"A Protocol Paper: Community engagement interventions for Cardiovascular Disorders prevention in socially disadvantaged populations in the UK: An implementation research study" Nahar.P et al (GHRP-D-19-00139R2) Journal of Global Health Research and Policy January 2020

ABCD Clinimetric Scale Revalidation

'Attitudes and Beliefs about Cardiovascular Disease (ABCD) Questionnaire'

Woringer M, Nielsen JJ, Zibarras L, *et al*
Development of a questionnaire to evaluate patients' awareness of cardiovascular disease risk in England's National Health Service Health Check preventive cardiovascular programme
BMJ Open 2017;**7**:e014413. doi: 10.1136/bmjopen-2016-014413

► Questionnaire guided by literature review, expert panel, patient focus group and data analysis. ► Largely developed among 110 individuals representative of the target population. ► Face validity assessed via a patient focus group not representative of the target population.

Revalidated by NTU with 450 SPICES participants

Clinical Trial Registration: ISRCTN68334579 : Heart health without a doctor: an implementation study of CVD prevention and behaviour change interventions in community settings
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