Original Article

A parallel-arm randomised control trial to study the effects of risk communication methods for prevention of cardiovascular diseases: EFFRICO trial

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Abstract

Introduction: Cardiovascular diseases (CVDs) have many risk factors; few can be modified through health education. Traditional patient counselling methods fail to impact health behaviours to prevent or reduce the risk of CVDs. **Objectives:** This study was conducted to estimate the effect of various risk communication methods on CVD risk reduction and medication adherence. **Design:** An open-label superiority randomised control trial was conducted where 159 patients were randomised into three groups: Communication of 10-year Framingham CVD risk score, heart age, and routine care. Follow-up was done 3 months after recruitment. The primary outcome was a difference in excess 10-year Framingham CVD risk score in the end-line compared to baseline. The status of modifiable behavioural risk factors at baseline was expressed as 'yes' and 'no', and follow-up was defined as 'action', 'positive maintenance', 'negative maintenance', and 'defaulter'. The trial was registered with the Clinical Trials Registry India (CTRI NO. CTRI/2020/10/028614). **Setting:** The study setting was screening outpatient department (OPD), General Medicine OPD, and Cardiology OPD of a tertiary care hospital in Central India. **Participants:** Participants aged >30 years, residing in Bhopal for more than 6 months, diagnosed with hypertension or diabetes mellitus or both, and having any of the four CVD behavioural risk factors: tobacco use, alcohol use, physical inactivity, or unhealthy diet. **Results:** Median excess 10-year Framingham CVD risk scores were 0.945% (CI: 1.275–4.297), –0.850% (–3.932–2.075), and –1.300% (–5.100–0.900) (10-year Framingham CVD risk score vs Heart age vs Routine care) and 0.000% (–3.125–5.925), –1.600% (–3.760–1.475), and –1.400% (–6.600–5.900) before and after intervention, respectively ($P > 0.05$). Positive maintenance was higher in both intervention groups concerning all modifiable behaviours, with a higher proportion reported in the 10-year Framingham risk score. The action phase was reported higher in intervention groups for medication adherence, addiction, and dietary changes. **Conclusion:** Systematic risk communication methods reduced the probability of contracting CVD in the future, though this finding was statistically insignificant.

Keywords: Behavioural risk factor, Framingham risk score, risk reduction

Introduction

Non-communicable diseases (NCDs) include cardiovascular diseases (CVDs), cancers, hypertension, diabetes, and chronic respiratory diseases, which are chronic and are noticeable during adulthood majorly, but the seeds are sown in the earlier years in the form of unhealthy lifestyles. They are influenced

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by a multitude of factors that are physiological, environmental, genetic, and behavioural.

The burden of CVDs: World and India

Although individuals of all age groups can be affected by NCDs, evidence shows that they are responsible for nearly 41 million deaths each year, out of which 15 million occur in the age group of 30–69 years. Low- and middle-income countries witness 85% of these premature deaths.[1] In India, 54.5 million are suffering from CVDs. This is led by ischemic heart diseases, contributing 61.4% to the total DALYs due to CVD, while stroke contributes 24.9%.[2] CVDs have many risk factors, such as raised blood pressure, diabetes, tobacco or alcohol use, high salt, sugar, and oil consumption, inadequate consumption of fruits and vegetables, physical inactivity, obesity, and raised cholesterol.

Prevention programmes in India

To curb the burden of NCDs, particularly CVDs, diabetes, and hypertension, the Government of India launched the National Programme for the Prevention and Control of Cancer, Diabetes, CVDs, and Stroke (NPCDCS) in 2010. After integration with the National Health Mission, the programme focussed on opportunistic and population-based screening of NCDs at various healthcare system levels. The programme enlists guidelines concerning medication and lifestyle modification through behaviour change to prevent and control CVDs and other NCDs. At operational levels, clinicians are the educators who inform patients about the condition, its risk factors, pharmacological treatment, and lifestyle modification.[3] The guidelines mentioned above are generic and lack individualistic personalisation. Furthermore, traditional patient education and counselling methods fall short in motivating patients to make desirable changes for managing their disease.[4] This leads us to a fundamental question, 'What information will make an impact?', that is, the content of these patient-clinician conversations.

Role of risk communication

Risk communication, defined as 'an interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers, and other interested parties', can play an important role in patient-doctor communication. Existing literature suggests that risk communication can play a pivotal role in the development and/or enhancement of accurate risk perception. Specific and selective information communicated methodologically is recommended to improve the accuracy of risk perception.[5] Various methods have been used to communicate the risk of CVDs such as heart age, JBS3 heart risk (Joint British Societies), 10-year Framingham CVD risk score, lifetime and 10-year ASCVD risk, QRISK2, and low-risk Systematic Coronary Risk Evaluation (SCORE) table. In addition, heart age has been used in various trials to educate patients about the risk of CVDs and has been found to perform better than risk scores.[6] The utilisation of interactive heart age tools can serve as an effective means of communication, encouraging individuals to make lifestyle adjustments to minimise risk factors.[7] These risk communication methods have been expressed numerically and pictorially, resulting in a significant reduction in the probability of developing CVDs, blood pressure, salt consumption, and tobacco usage.[8-10] Apart from these, information, education, and communication (IEC) have also been used for communicating the risk in the form of counselling, posters, discussions, etc., based on behaviour change models such as planned behaviour theory, social cognitive theory, and self-regulation theory.[4,11] IEC has been incorporated in the programmatic guidelines of NPCDCS but without any defined standard operating procedure. Formal risk communication methods have been experimented with noteworthy results regarding CVD risk and risk factor reduction. Indian settings have not yet been experimented with regarding the risk communication methods mentioned above. Given the burden of CVD in India and the grave possibility of NCDs being labelled as a pandemic, it calls for prompt and clear-cut actions in this direction.[12] This concept along with the hard-hitting evidence led to designing and conducting this study to estimate the effect of various risk communication methods in terms of CVD risk reduction, medication adherence, and behavioural risk factor status. This randomised control trial is a first of its kind as the intervention was given in Hindi language.

Methods

Study Setting

The study setting was screening outpatient department (OPD), General Medicine OPD, and Cardiology OPD of a government-run tertiary healthcare institute in central India.

Selection criteria

Participants of more than 30 years of age, residing in Bhopal for more than 6 months, diagnosed with hypertension or diabetes mellitus or both, and having any of the four CVD behavioural risk factors, namely tobacco use, alcohol use, physical inactivity, or unhealthy diet, were included. Exclusion criteria included participants with a history of any known CAD/IHD/STROKE (verified through written medical prescription or self-reported angiography, DSA, stent, by-pass, etc.), any known congenital heart diseases (verified through written medical prescription or self-reported frequent pneumonia, blue discoloration, etc.) and any RHD, valve diseases (verified through written medical prescription or self-reported regular painful injections, etc.)

Study design

A parallel open-label superiority randomised control trial was conducted to estimate the effect of the two risk communication methods, that is, communication of 10-year Framingham CVD risk score and heart age, against standard care.[13] As the interventions involved communication of risk score, blinding participants and the investigator was impossible. However, allocation concealment was taken care of by using sequentially numbered opaque sealed envelopes to randomise participants into the three arms of the trial. Block randomisation was performed

using online software. The trial was registered with the Clinical Trials Registry India (CTRI NO. CTRI/2020/10/028614). The study was approved by AIIMS, Bhopal Institute Human Ethics for Post-graduate Research (AHEC-PGR) committee (LOP: IHECPGRMD026).

Patient and Public Involvement: There was no patient and public involvement in this study.

Sample size

The sample size for the randomised control trial calculated using G power software for two intervention groups and one control group with an effect size of 0.4, 5% type I error, and 80% power came out to be 51 for each group. We anticipated a 20% loss-to-follow-up in each group. Therefore, we planned to recruit 61 participants in each group.

Intervention

The intervention consisted of risk communication about CVDs where information about the risk was communicated to the participants. Risk of CVDs were communicated in the form of two scores in the two intervention arms, that is, 10-year CVD Framingham risk score and heart age.[13] A standard of procedure (SOP) was developed for administering the intervention in Hindi [Supplementary File 1]. Two consenting interventionists (medical social worker and senior resident) were trained using the developed SOPs.

Data collection

A survey tool was developed to capture the baseline information of participants about the physical parameters and modifiable behavioural risk factor status. It was translated to Hindi followed by expert and peer validation. Subsequently, the questionnaire was pilot-tested on 20 individuals not part of the study setting to detect any ambiguity or technical errors. Complex vocabulary and sentences were reframed. With due permission, a daily OPD list containing participants' details was obtained from the registration counter. Participants fitting the age and residency criteria were called via mobile and confirmed for the remaining inclusion criteria. In total, 985 participants were approached via phone call and 256 were found to be eligible, of which 159 consented to be a part of the trial, and recruitment was done from January 2021 till May 2021. These participants were given appointments to visit the screening OPD for recruitment. When they reported, a participant information sheet was given, followed by consent from interested participants. Baseline information, including physical parameters (weight, height, and blood pressure), was collected, after which an opaque sealed envelope was given to the participant. Participants were directed to a subordinate staff who supervised the opening of envelopes and directed the participants to the respective intervention cabins. The physician posted in the screening OPD addressed any queries post this procedure. A follow-up survey tool was developed, derived from the baseline survey tool. Follow-up was done through phone calls three months after the recruitment for each participant. Figure 1 illustrates the flow of the trial.

Primary outcome

The primary outcome was expressed as a difference in excess 10-year Framingham CVD risk score from baseline. The excess risk was calculated as the difference between the participant's actual risk score and the score of a reference individual of the same age.

Secondary outcome

The secondary outcome was the change in the status of eight modifiable risk factors. The status of modifiable behavioural risk factors at baseline was expressed as 'yes' and 'no', corresponding to 'engaging in behaviour' and 'not engaging in behaviour', respectively. Table S1 depicts the status at follow-up, which was defined as 'action', 'positive maintenance', 'negative maintenance', and 'defaulter'.

Statistical analysis

The data were entered into a Microsoft Excel sheet and coded appropriately. Analysis was performed in IBM SPSS Statistics Version 26. Categorical variables were expressed as frequencies and percentages. An intention-to-treat analysis was performed.[14] Wilcoxin signed rank test was performed to assess the difference in excess 10-year Framingham CVD risk score in the three intervention arms before and after the intervention. Change in behaviour status was compared across the three arms of the trial using Fisher's exact test, and *P*-value of <0.05 was taken as statistically significant.

Ethics

Permission was taken from the institutional ethics committee before the commencement of the study (LOP No.: IHECPGRMD026, dated 23rd June 2020). A detailed participant information sheet was given, followed by written informed consent for interested participants. There were no invasive procedures involved in the trial. Participant data were kept in password-protected computers/laptops. Personal identifiers were removed during the analysis and reporting of data. Adverse events such as unfavourable and unintended symptoms or diseases related to this study were not detected.

Results

At baseline, 60 participants were randomised into the 10-year Framingham CVD risk score group, 61 participants to heart age, and 38 participants to the control group [Table 1]. Groups were comparable at baseline, with no statistically significant differences among them. Table S2 depicts the distribution of study participants as per their status of modifiable behavioural risk factors at baseline, assessed as whether a particular behaviour was being followed. At baseline, a more significant number of participants were following desirable behaviours such as medication adherence, regular physical activity, and consumption of fruits and vegetables. On the contrary, the majority were not following undesirable behaviours such as tobacco and alcohol use and high sugar, oil, and salt consumption. Twenty participants

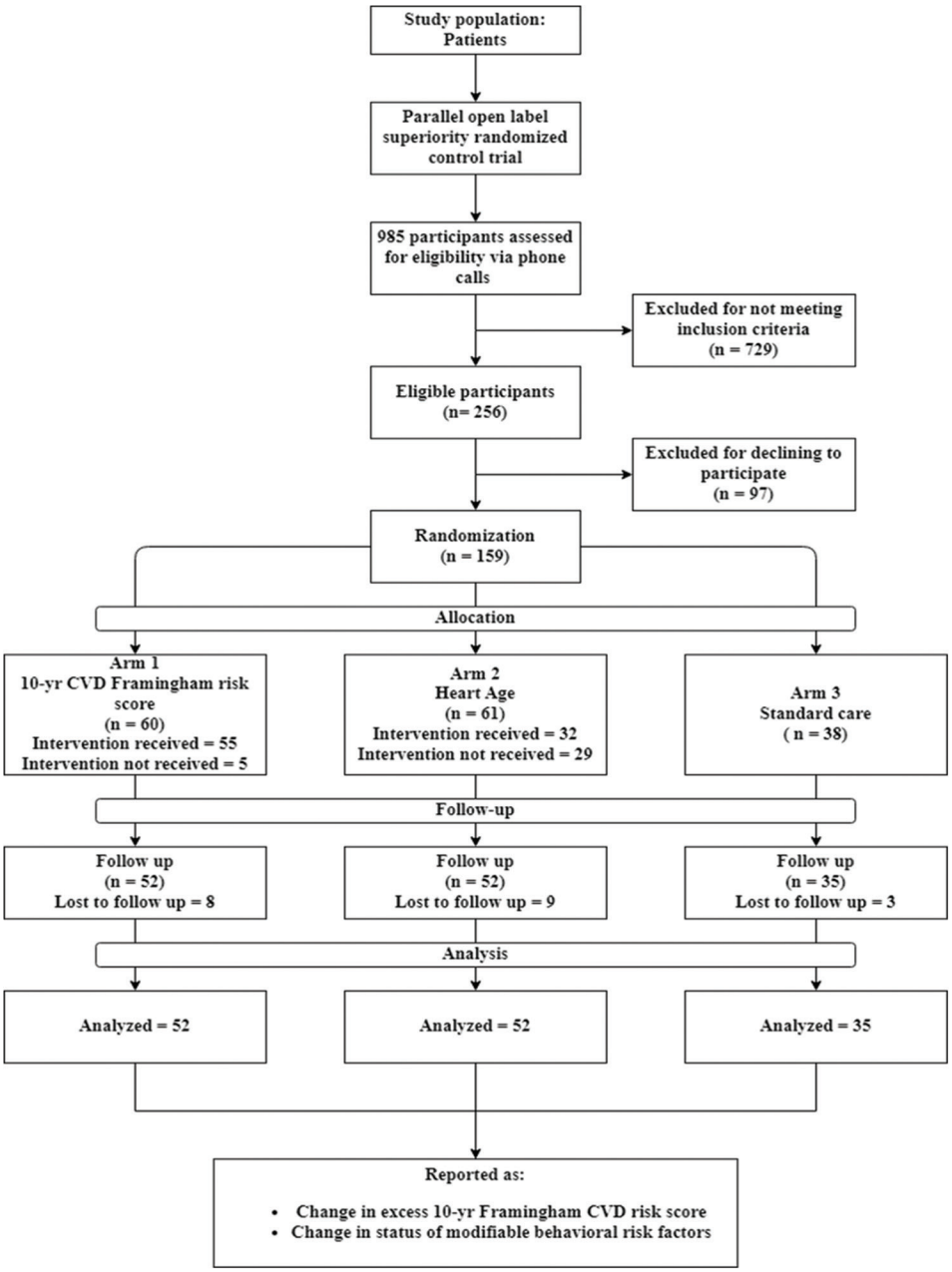

Figure 1: Flowchart illustrating flow of the trial

were lost to follow-up, out of which six had expired and the rest of the 14 participants did not respond.

Primary outcome

The primary outcome, that is, excess 10-year Framingham CVD risk score, was expressed as a median, interquartile range, and means standard deviations. The median excess 10-year Framingham CVD risk score was 0.945% (CI: −1.275–4.297), −0.850% (CI: −3.932–2.075), and −1.300% (CI: −5.100–0.900) (10-year Framingham CVD risk score vs Heart age vs Routine care) and 0.000% (CI: −3.125–5.925), −1.600% (CI: −3.760–1.475), and −1.400% (CI: −6.600–5.900) before and after intervention, respectively. Figure S1 illustrates the trends in median excess 10-year Framingham CVD risk scores on a box plot. As the data were skewed for all the variables, a Wilcoxin signed rank test was performed, and the median excess 10-year Framingham CVD risk score was lower after the intervention in all three trial arms, but it was statistically insignificant ($P = 0.332$, $P = 0.261$, and $P = 0.225$ in 10-year Framingham CVD risk score vs Heart age vs Routine care, respectively).

Secondary outcomes

Change in behaviour status was compared across the three arms of the trial by using Fisher's exact test, and *P*-value of <0.05 was taken as statistically significant. Table 2 depicts the trial arm-wise distribution of the status of modifiable behavioural

Table 1: Baseline sociodemographic characteristic of study participants by trial arm

Sociodemographic characteristics	Trial arms (*n*=159)			*P*
	10-year Framingham CVD risk score (*n*=60)	Heart age (*n*=61)	Control (38)	
Gender				
Male	34 (37%)	34 (37%)	24 (26.1%)	0.746
Female	26 (38.8%)	27 (40.3%)	14 (20.9%)	
Age				
30–49	25 (42.4%)	22 (37.3%)	12 (20.3%)	0.174
50–69	32 (36.8%)	36 (41.4%)	19 (21.8%)	
69 & above	3 (23.1%)	3 (23.1%)	7 (53.8%)	
Education				
Above matriculation	33 (34.7%)	38 (40%)	24 (25.3%)	0.634
Matriculation & below	27 (42.2%)	23 (35.9%)	14 (21.9%)	
Occupation				
Employed	35 (40.2%)	32 (36.8%)	20 (23%)	0.775
Unemployed	25 (34.7%)	29 (40.3%)	18 (25%)	
Marital status				
Married	53 (39.6%)	49 (36.6%)	32 (23.9%)	0.481
Unmarried & others	7 (28%)	12 (48%)	6 (24%)	
Socioeconomic class				
Upper I	4 (66.7%)	2 (33.3%)	0	0.501
Upper Middle II	11 (33.3%)	12 (36.4%)	10 (30.3%)	
Lower middle III	19 (47.5%)	15 (37.5%)	6 (15%)	
Upper lower IV	20 (31.3%)	27 (42.2%)	17 (26.6%)	
Lower V	6 (37.5%)	5 (31.3%)	5 (31.3%)	

risk factors. Participants were maximally found to be in positive maintenance in all three groups with regard to the consumption of fruits and vegetables. Positive maintenance was highest in the 10-year Framingham risk score group compared to the other two groups, which was statistically significant ($P = 0.00$). Similarly, maximum participants were in positive maintenance for high salt consumption, and it was the highest in the 10-year Framingham risk score group, which was statistically significant ($P = 0.00$). For high sugar consumption, maximum participants were in positive maintenance after 3 months of intervention, and it was the highest in the 10-year Framingham risk score group, which was statistically significant ($P = 0.04$). Lastly, high oil consumption also presented with maximum participants in positive maintenance, and it was the highest in the 10-year Framingham risk score group, which was statistically significant ($P = 0.00$). Figure 2 depicts the movement of modifiable behavioural risk factors. Each modifiable behavioural risk factor saw a few participants in the action stage at follow-up.

Discussion

Risk communication

In this study, healthcare can be considered a commodity that a healthcare provider like a physician, surgeon, nurse, or social worker provides to beneficiaries, essentially patients. As a commodity, it involves diagnostic and treatment services. Treatment might involve medical prescriptions, surgical procedures, and health education and promotion. Healthcare providers use diverse techniques to advise and motivate about medication and any lifestyle changes concerning CVDs. Sometimes, the advice is generic and mechanical; other times, it is personalised to fit the patient's existing routine, job, and demographic profile.[15] Given the high load of patients in Indian OPD departments, healthcare providers usually do not find the time to give elaborate details about the disease and course of treatment.[16] They try to utilise the consultation time to give the relevant information maximally. With much reluctance, they have to shorten the communication part to be able to cater to all the patients visiting them.[17]

EFFRICO trial vs other similar trials

The randomised control trial performed in this study included two risk communication methods, that is, 10-year Framingham CVD risk score and heart age, which was compared with routine care. The excess 10-year Framingham CVD risk scores showed a slightly decreasing trend in all three trial arms over 3 months after the intervention. A similar trial, The Risk Evaluation and Communication Health Outcomes and Utilisation Trial (REACH OUT), reported a reduction in the predicted 10-year risk of CHD in the intervention group over 6 months after they were communicated their predicted 10-year risk of CHD and were educated about modifiable risk factors and their management.[18] Another trial comparing communication of Framingham REGICOR and heart age with routine care reported a significant decrease in Framingham risk scores in both the intervention groups, with the heart age group performing better.[6] Our findings also reported a greater decreasing trend in the median 10-year Framingham CVD risk scores in the 10-year Framingham CVD risk score group as compared to the other two groups. The routine care group had the minimum apparent reduction in the scores. There may be differential stimulus for information processing working in an individualistic manner

Table 2: Trial arm wise distribution of status of modifiable behavioural risk factors

	(*n*=139)				
	Medication adherence				
Study groups	**Action**	**Positive maintenance**	**Negative maintenance**	**Defaulter**	***P***
10-year Framingham risk score	7 (13.5%)	42 (80.8%)	1 (1.9%)	2 (3.8%)	0.1840
Heart age	4 (7.7%)	41 (78.8%)	6 (11.5%)	1 (1.9%)	
Routine care	2 (5.7%)	32 (91.4%)	0	1 (2.9%)	
Regular physical activity					
10-year Framingham risk score	3 (5.8%)	27 (51.9%)	21 (40.4%)	1 (1.9%)	0.0709
Heart age	6 (11.5%)	19 (36.5%)	25 (48.1%)	2 (3.8%)	
Routine care	6 (17.1%)	8 (22.9%)	17 (48.6%)	4 (11.4%)	
Consumption of fruits & vegetables					
10-year Framingham risk score	4 (7.7%)	43 (82.7%)	4 (7.7%)	1 (1.9%)	**0.0010**
Heart age	5 (9.6%)	37 (71.2%)	10 (19.2%)	0	
Routine care	5 (14.3%)	15 (42.9%)	15 (42.9%)	0	
Tobacco usage					
10-year Framingham risk score	3 (5.8%)	37 (71.2%)	10 (19.2%)	2 (3.8%)	0.4570
Heart age	3 (5.8%)	42 (80.8%)	7 (13.5%)	0	
Routine care	2 (5.7%)	22 (62.9%)	9 (25.7%)	2 (5.7%)	
Alcohol usage					
10-year Framingham risk score	0	51 (98.1%)	1 (1.9%)	0	0.9213
Heart age	1 (1.9%)	49 (94.2%)	1 (1.9%)	1 (1.9%)	
Routine care	0	35 (100%)	0	0	
High salt consumption					
10-year Framingham risk score	3 (5.8%)	48 (92.3%)	1 (1.9%)	0	**0.0000**
Heart age	9 (17.3%)	37 (71.2%)	4 (7.7%)	2 (3.8%)	
Routine care	10 (28.6%)	16 (45.7%)	9 (25.7%)	0	
High sugar consumption					
10-year Framingham risk score	2 (3.8%)	50 (96.2%)	0	0	**0.0446**
Heart age	6 (11.5%)	42 (80.8%)	2 (3.8%)	2 (3.8%)	
Routine care	0	34 (97.1%)	1 (2.9%)	0	
High oil consumption					
10-year Framingham risk score	6 (11.5%)	44 (84.6%)	1 (1.9%)	1 (1.9%)	**0.0002**
Heart age	17 (32.7%)	28 (53.8%)	5 (9.6%)	2 (3.8%)	
Routine care	1 (2.9%)	33 (94.3%)	1 (2.9%)	0	

Boldface indicates statistical significance ($P<0.05$)

as evident in our study. Although the two methods essentially communicate the cardiovascular risk, individuals may perceive 'longitudinal' and immediate time frame component differently. The REACH OUT trial also reported a significant reduction in blood pressure and low-density lipoprotein cholesterol. Apart from this, participants in the intervention group also quit smoking.[19] Similarly, when the status of modifiable behavioural risk factors was compared at baseline and follow up, maximum participants maintained (positive maintenance) following of desirable behaviours and discontinuation of undesirable behaviours. Few participants also acted in favour of the former and against the latter. Positive maintenance was higher in the 10-year Framingham risk score and heart age group concerning all modifiable behaviours with a higher proportion reported by the former. However, it has been recommended that when presented in interactive forms, heart age may help patients reduce their risk factors more than absolute risk assessment.[7] The action was also reported higher in the intervention groups for medication adherence, tobacco and alcohol usage, and high salt and sugar consumption. The results reported across various risk communication trials, and our findings suggest that risk communication in the form of cardiovascular risk scores can prove to be helpful in clinical practices.

Implications

In orientation with behaviour change models, risk communication is expected to shape the risk perception, which will lead to behaviour change. The @RISK study also plans to explore this very concept in its trial. They plan to assess the appropriateness of risk perception and intention to change lifestyle behaviours in patients when they are communicated about 10-year probabilities of CVDs.[4] The gap in knowledge about precise and relevant information that should be communicated to patients to have better health outcomes has been proven to be filled by risk communication.[21] Different risk scores used in this study or elsewhere can be used for impactful physician-patient communication.

Limitations

Unprecedented events of the COVID-19 pandemic interrupted the recruitment and intervention of participants for the

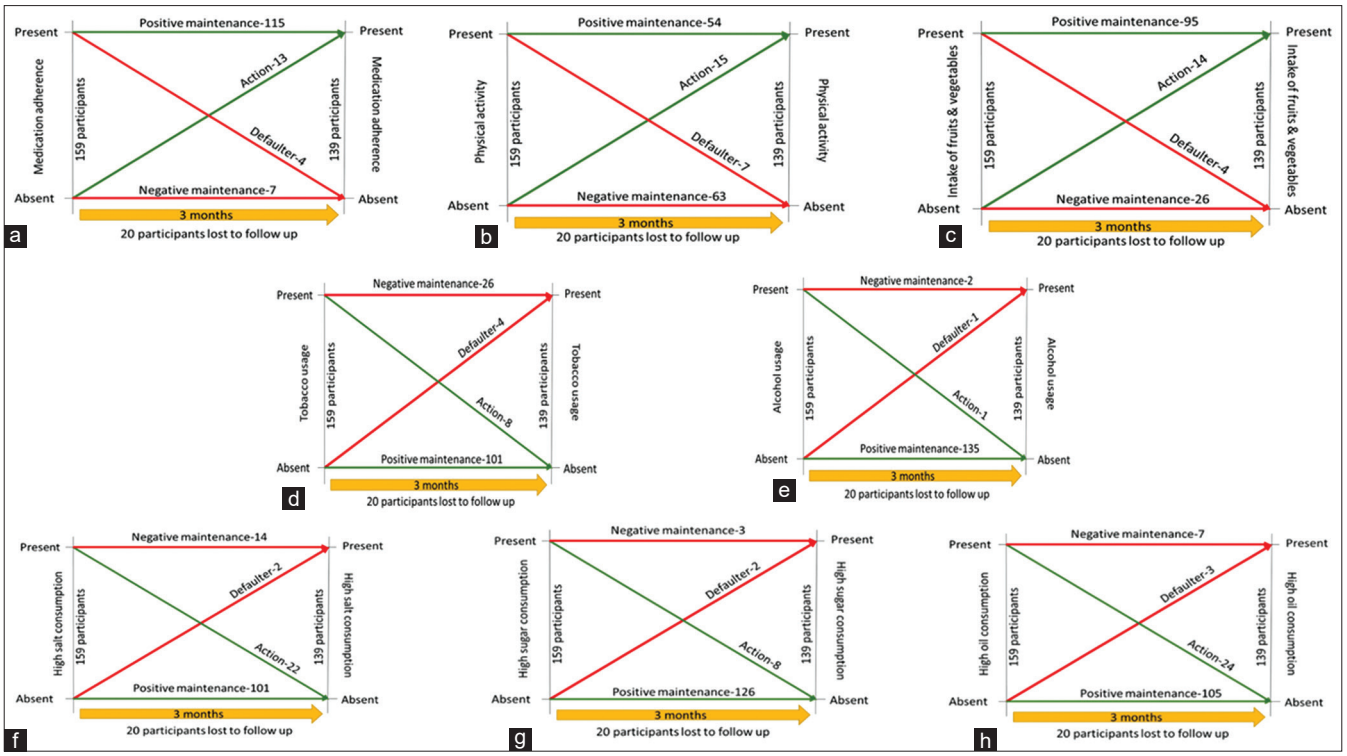

Figure 2: (a-h) Behaviour change from baseline to follow up over 3 months for (a) medication adherence, (b) Physical activity, (c) Consumption of fruits and vegetables, (d) tobacco usage, (e) Alcohol usage, (f) High salt consumption, (g) High sugar consumption, (h) High oil consumption

randomised control trial, as a result of which a specified sample size could not be achieved. In addition, as this was a dissertation, feasibility issues led to the shortening of the follow-up period, which might have affected the outcome measures of the trial in unpredictable ways. Similar reasons led to the inability to study and evaluate any outlier cases in the trial. Modifiable behaviour status was self-reported; hence, it might have led to social desirability bias.

Conclusion

Precise information, in numerical terms, about the risk of CVDs was communicated, and it impacted certain modifiable behaviours. There was no significant difference in the excess 10-year Framingham CVD risk scores between intervention and control groups, possibly due to the limitations in sample size and the duration of the follow-up period. However, patient perceptions should be evaluated before initiating risk communication with them. As learning can be visual, auditory, or kinaesthetic, a package containing a hybrid of various risk communication techniques can be explored in this context. The intervention in this study, that is, risk was communicated in Hindi, making it the first of its kind in the field of risk communication in CVDs.

1.What is already known on this topic

Traditional patient education and counselling methods fall short in motivating patients to adopt healthy behaviours for preventing cardiovascular diseases (CVDs). Formal risk communication methods have been experimented with noteworthy results regarding CVD risk and risk factor reduction.

2.What does this study add?

Indian settings had not yet been experimented with the risk communication methods mentioned above. Precise information, in numerical terms, about the risk of CVDs was communicated, and it impacted certain modifiable behaviours. The intervention in this study, that is, risk, was communicated in Hindi, making it the first of its kind in the field of risk communication in CVDs.

3.How this study might affect research, practice, or policy?

In orientation with behaviour change models, risk communication is expected to shape the risk perception, which will lead to behaviour change. Different risk scores used in this study or elsewhere can be used for impactful physician-patient communication.

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Conflicts of interest

There are no conflicts of interest.

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Table S1: Movement of modifiable behavioural risk factors

Behaviour risk factors	Status of behaviour (baseline → follow up)			
	Action	Positive maintenance	Negative maintenance	Defaulter
Medication adherence	No → Yes	Yes → Yes	No → No	Yes → No
Regular physical activity	No → Yes	Yes → Yes	No → No	Yes → No
Consumption of fruits and vegetables	No → Yes	Yes → Yes	No → No	Yes → No
Tobacco use	Yes → No	No → No	Yes → Yes	No → Yes
Alcohol use	Yes → No	No → No	Yes → Yes	No → Yes
Consumption of high salt	Yes → No	No → No	Yes → Yes	No → Yes
Consumption of high sugar	Yes → No	No → No	Yes → Yes	No → Yes
Consumption of high oil	Yes → No	No → No	Yes → Yes	No → Yes

Table S2: Distribution of study participants as per their status of modifiable behavioural risk factors before the intervention

Modifiable behavioural risk factor	Frequency (%) (*n*=159)
Medication adherence	
Yes	132 (83%)
No	27 (17%)
Regular physical activity	
Yes	72 (45.3%)
No	87 (54.7%)
Consumption of fruits & vegetables	
Yes	113 (71.1%)
No	46 (28.9%)
Tobacco usage	
Yes	42 (26.4%)
No	117 (73.6%)
Alcohol usage	
Yes	3 (1.9%)
No	156 (98.1%)
High salt consumption	
Yes	132 (83%)
No	27 (17%)
High sugar consumption	
Yes	14 (8.8%)
No	145 (91.2%)
High oil consumption	
Yes	34 (21.4%)
No	125 (78.6%)

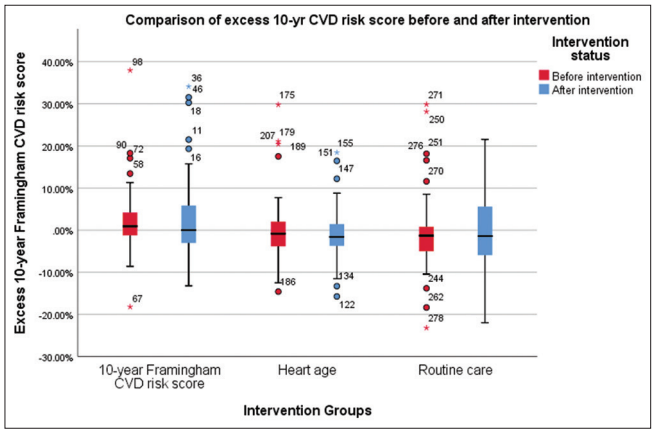

Figure S1: Trends in median excess 10-year Framingham CVD risk scores across intervention and control groups