

doing good to a fellow human needs to be weighed against all potential risks—in this case unique to women, the weaker gender at least in developing societies.

In the rush to transplant more and more patients with end-stage kidney failure, the woman donor usually receives the short shrift, treated only as a source of a kidney. Often she is assured in a casual manner that donation poses no risk and that she can expect to live a life she has a right to expect had she not volunteered to be a donor.

These recent publications are of particular importance to societies where most donors do not have access to good quality medical care.^{7,8} This makes them even more vulnerable to the potential ill-effects of organ donation. It is time that all transplant centres established 'donor advocates' who are primarily responsible for the welfare of the donor and provide them with all the information they need before deciding to become a live kidney donor.

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VIVEKANAND JHA

Department of Nephrology

Postgraduate Institute of Medical Education and Research

Chandigarh

vjha60@gmail.com

Community health worker-based intervention for diabetes care: Feasibility and cultural acceptability in India

Palmas W, Findley SE, Mejia M, Batista M, Teresi J, Kong J, Silver S, Fleck EM, Luchsinger JA, Carrasquillo O. (Columbia University Medical Center, New York; Columbia University Mailman School of Public Health, New York; Alianza, New York; Research Division, Hebrew Home for the Aged at Riverdale, Bronx, New York; Columbia University, New York; Division of General Internal Medicine, University of Miami Miller School of Medicine, Miami, Florida, USA.) Results of the Northern Manhattan Diabetes Community Outreach Project: A randomized trial studying a community health worker intervention to improve diabetes care in Hispanic adults. *Diabetes Care* 2014;**37**:963–9.

SUMMARY

A randomized controlled trial evaluated whether a community health worker (CHW)-based intervention could improve clinically relevant markers of diabetes care in an adult underserved Hispanic community in Manhattan, New York, USA. The primary outcome was glycosylated haemoglobin (HbA1c) while the secondary outcomes were systolic blood pressure (SBP), diastolic blood pressure (DBP) and low-density lipoprotein (LDL)-cholesterol. Outcomes were measured at baseline and at the end of one year. The lifestyle intervention was based on the 'small steps, big rewards' programme, which included dietary modification and increasing physical activity to decrease the progression of high-risk individuals to diabetes. Participants included underserved Hispanics receiving care at one of the designated primary care centres under Columbia University Medical Centre, aged 35–70 years, with poor glycaemic control (HbA1c >8%). The study excluded

those with type 1 diabetes, diabetes with onset before the age of 25 years, diagnosed for less than one year, any extreme medical comorbid condition, arm circumference >47 cm, planning to move out of the neighbourhood during the next year or those enrolled in any other ongoing study.

The participants were remotely randomized within each primary care-provider using statistical package SAS by an operator who was blinded to all participant characteristics except being aware of the provider. The intervention arm provided four one-to-one visits in the first 2 months, followed by monthly group sessions and follow-up phone calls in the remaining 10 months, whereas the control arm provided usual care along with educational material in Spanish and quarterly phone calls. Analysis was done using SAS software. The longitudinal mixed effects model was used and intention-to-treat analysis was done using multiple imputation sensitivity analysis. Of the 181 participants randomized to intervention and another 179 to the control arm, 18.8% and 12.3%, respectively were lost to follow-up. No clinically meaningful differences between the study groups were found at baseline. In the intervention arm, a median of 3 (interquartile range 4–2) one-on-one meetings, 0 (4–0) group sessions, and 10 (14–7.5) phone calls were conducted. However, 93 participants received only a phone-based intervention.

Although the primary outcome, HbA1c, showed a trend towards reduction, neither primary nor secondary outcomes differed significantly between the intervention and control arms. The number of phone calls, however, showed an association with a reduction in HbA1c levels ($p=0.04$). With regard to change in HbA1c, similar effects of the intervention were seen in those who had optimal glycaemic control (baseline HbA1c <7%, $n=46$) versus those who did not (baseline HbA1c $\geq 7\%$, $n=314$). The results of sensitivity analyses that compensated for missing data through different models did not vary substantially from the intention-to-treat findings.

COMMENT

This well-rationalized study evaluated the interventions led by CHWs, which is likely to be the fulcrum of many programmes for

the control of diabetes worldwide. We critically appraised the study in terms of its strengths, whether it had internal validity, the generalizability of the findings, whether the study design was appropriate and could there be an alternative explanation for the findings.

The strengths of the study included the attempt to evaluate CHW-led interventions for diabetes control and prevention. The study had objectively measured end-points, and used robust statistical methods to account for missing data.

Internal validity of a study is affected among other issues by systematic differences over conditions in respondent characteristics, which could cause the observed effect.¹ The 'small steps, big rewards' programme has been advocated for prevention of diabetes in people who are at high-risk of developing diabetes, and not for those with poorly controlled diabetes, which was one of the inclusion criteria in the study. We highlighted this issue in our correspondence published in *Diabetes Care*.² The authors of the main study in their reply³ argued it to be an 'innovation in science'.

The sample size, detailed in the supplement of the main article, with a level of significance of 5%, power of 80% to detect a 0.51 unit change in HbA1c discounting for an attrition rate of 30%, was calculated as 170 participants per arm. However, with the specified values and formulae stated in the supplement of the article, this equals 355 participants per arm. With the sample size actually used in the study, it had 80% power to detect a larger (i.e. 0.75 unit) change in HbA1c levels. The authors in reply³ to our correspondence² stated '...we do agree with the concern regarding the lack of statistical power, which we believe was mostly due to lower-than-expected intervention fidelity...'

In addition, the authors have analysed results stratified by baseline HbA1c levels (<7 or ≥7%) although the inclusion criteria was HbA1c >8%. Accepting this issue, the authors noted³ that '... in retrospect, obtaining a point-of-care HbA1c measurement and restricting enrolment to those with elevated HbA1c might have been a better approach than the one we took...'

Poor adherence to the study protocol, especially in the intervention arm where almost one-third (37%) did not receive the intervention component of the phone call and another nearly 50% did not receive any of the planned one-on-one or small subgroup sessions, could have resulted in the non-significant findings. The authors replied³ it to be due to '... a great difficulty by the participants in attending the pre-specified in-person sessions...'

The authors have used robust statistical techniques including sensitivity analysis to counter this methodological limitation and concluded that the phone-based intervention had a significant effect. However, due to reasons mentioned earlier, such a conclusion is questionable. In addition, contamination of the usual care arm due to simultaneous initiatives is also likely to affect the internal validity of the study.

Constrained by participants' race, socioeconomic status (urban, underserved, Hispanic), gender (almost 60% were women) and with disability (almost 40% were on disability allowance), the findings of the study cannot be generalized to the population at large.

We believe that CHW-led interventions are dependent on training received by the CHWs and their performance. Hence, in real-life scenarios, such 'information-based interventions' to be imparted by a CHW would be difficult to randomize for individuals. Moreover, when only a small sample size is available to test the efficacy of an intervention, randomization may not be viable due to inadequate power. In such situations, a quasi-experimental

study design that aims to evaluate the intervention can be used to show causality between an intervention and outcomes.

Implications for India

In 2013, there were 65.1 million people with diabetes in India⁴ and the number is expected to rise to 101.2 million by 2030.⁵ Diab-Care Asia, a multicountry study in Asia in 2001, showed that 50% of people with diabetes were poorly controlled as measured by HbA1c.⁶ Both patients and medical practitioners lacked understanding of the need for constant disease monitoring and adopting a consistent approach to glycaemic control.⁷

There is evidence to show that lifestyle interventions can prevent diabetes. A meta-analysis done in 2003 shows that behavioural and educational interventions were effective in reducing HbA1c by 0.43%, fasting blood glucose by 24 mg/dl and weight by 3 lb.⁸ Some studies have reported that CHWs have the potential to enable this change,⁹ especially among socially disadvantaged populations.¹⁰ A systematic review of 18 studies done in 2010 showed that CHW interventions for diabetes improved participant knowledge, physiological measures for some interventions and brought about positive changes in lifestyle and self-care.¹¹

Only a few studies have evaluated the efficacy of these measures in the Indian setting. A study in Gujarat among 1638 rural Indians that evaluated the effect of culturally and linguistically appropriate health education messages through individual and group sessions found significant reduction in blood glucose levels, obesity and systolic and diastolic blood pressure. Knowledge of diabetes and cardiovascular disease also improved.¹²

The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke¹³ includes opportunistic screening, health education and health promotion activities. However, its dissemination at the individual level in the community is a challenge. Involvement of non-governmental organizations (NGOs) can help reduce the burden on the government. Some have advocated that involving NGOs is cost-effective, especially for counselling and rehabilitation. This can also overcome the problem of non-availability of trained personnel in rural areas.¹⁴ Such organizations can perhaps sensitize families about providing vital social support which improves the perceived quality of life and patients ability to cope with the disease.¹⁵ Further studies regarding feasibility and cultural acceptability of CHW interventions are required in India for formulating evidence-based policies.

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VIVIKTHA RAMESH

PARTHA HALDAR

SHASHI KANT

Centre for Community Medicine
All India Institute of Medical Sciences

New Delhi

drparthohaldar@gmail.com

Should birth preparedness and complication readiness (BPCR) interventions be scaled up in developing countries?

Soubeiga D, Gauvin L, Hatem MA, Johri M. (Department of Health Administration; Department of Social and Preventive Medicine Faculty of Medicine, University of Montreal; Division of Global Health, University of Montreal Hospital Research Centre [CRCHUM], Montreal, Canada.) Birth preparedness and complication readiness (BPCR) interventions to reduce maternal and neonatal mortality in developing countries: Systematic review and meta-analysis. *BMC Pregnancy Childbirth* 2014;**14**:129.

SUMMARY

This meta-analysis aimed to put together evidence on effectiveness of birth preparedness and complication readiness (BPCR) interventions on maternal and neonatal mortality. BPCR activities cover antenatal, intranatal, postnatal and neonatal periods with the strategy to inform mothers about location of emergency services, potential occurrence of obstetric complications and signs of complications, encourage the mother to take decisions before the onset of labour and to save money needed to pay for services and, finally, be able to take decisions during an emergency or complications.¹ The intervention was BPCR, which could be any individual intervention or any of the above components combined, received by pregnant women residing in developing nations. In the comparator group were women who did not receive any BPCR interventions. The primary outcomes were maternal mortality ratio (MMR) and neonatal mortality rates (NMR) while the secondary outcomes were process indicators such as use of skilled services, and hygienic practices in the home. The review included randomized controlled trials; the level of randomization was either at the individual or at the cluster level. Articles published in French or English language were considered. Major search engines were used to look for relevant articles. Finally, 14 studies were selected and the quality ascertainment was done using McMaster Quality Assessment Tool. Meta-analysis was done to combine relative risks (RR), and a random effects model was used. Data were re-analysed on the basis of the intention-to-treat principle. Combinations

were carried out using the Mantel–Haenszel method.

A total of 307 018 women participants, with 292 256 live-births were included in the meta-analysis. Maternal mortality was measured in only seven studies. There was 28% reduction in RR of maternal mortality but this was non-significant (RR 0.72; 95% CI 0.46, 1.13). In subgroup analysis where at least 30% of targeted women participated in interventions, there was significant reduction of 53% in maternal mortality risk (four studies, RR 0.47; 95% CI 0.26, 0.87).

Neonatal mortality was measured in 12 studies. There was a significant reduction of 18% in RR of neonatal mortality (RR 0.82; 95% CI 0.74, 0.91). In subgroup analysis (9 studies where at least 30% of targeted women participated in interventions) there was statistically significant reduction of 24% in NMR (RR 0.76; 95% CI: 0.69, 0.85). Two trials that combined home visits with community-based group sessions showed a higher reduction in NMR (RR 0.68; 95% CI 0.40, 0.98) compared to either of them alone—home visits strategy (RR 0.86; 95% CI 0.79, 0.94), community-based group sessions (RR 0.83; 95% CI 0.70, 0.98). The neonatal mortality risk decreased by 25% (RR 0.75; 95% CI 0.63, 0.89) in trials where the NMR in the control group was >40/1000.

There was improvement in some process outcomes associated with child survival such as the use of care in the event of newborn illness (RR 1.66; 95% CI 1.23, 2.25), practice of clean cutting of the umbilical cord (RR 1.33; 95% CI 1.14, 1.55) and breastfeeding within the first hour after birth (RR 1.79; 95% CI 1.27, 2.51).

COMMENT

This meta-analysis showed that BPCR intervention reduced the NMR and more so in the group with baseline NMR >40/1000 live-births. It also improved care in the event of newborn illness, practice of clean cutting of the umbilical cord and breastfeeding within the first hour after birth. The effect on maternal mortality reduction was not significant.

The ascertainment of quality is an important component while reviewing and including studies in a meta-analysis. It was found that blinding to the outcome assessment was missing in most studies being adequate in only three studies. This could lead to bias and thus future trials conducted with similar interventions should include blinding of outcome assessment. All published studies have been included in this meta-analysis, and the possibility of publication bias could not be ruled out. The results had