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Short Report: Care Delivery

Efficacy of a virtual assistance-based lifestyle intervention in reducing risk factors for Type 2 diabetes in young employees in the information technology industry in India: LIMIT, a randomized controlled trial

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Abstract

Aims To investigate a virtual assistance-based lifestyle intervention to reduce risk factors for Type 2 diabetes in young employees in the information technology industry in India.

Methods LIMIT (Lifestyle Modification in Information Technology) was a parallel-group, partially blinded, randomized controlled trial. Employees in the information technology industry with ≥3 risk factors (family history of cardiometabolic disease, overweight/obesity, high blood pressure, impaired fasting glucose, hypertriglyceridaemia, high LDL cholesterol and low HDL cholesterol) from two industries were randomized to a control or an intervention (1:1) group. After initial lifestyle advice, the intervention group additionally received reinforcement through mobile phone messages (three per week) and e-mails (two per week) for 1 year. The primary outcome was change in prevalence of overweight/obesity, analysed by intention to treat.

Results Of 437 employees screened (mean age 36.2 ± 9.3 years; 74.8% men), 265 (61.0%) were eligible and randomized into control (n=132) or intervention (n=133) group. After 1 year, the prevalence of overweight/obesity reduced by 6.0% in the intervention group and increased by 6.8% in the control group (risk difference 11.2%; 95% CI 1.2–21.1; P=0.042). There were also significant improvements in lifestyle measurements, waist circumference, and total and LDL cholesterol in the intervention group.The number-needed-to-treat to prevent one case of overweight/obesity in 1 year was 9 (95% CI 5–82), with an incremental cost of INR10665 (£112.30) per case treated/prevented. A total of 98% of participants found the intervention acceptable.

Conclusions A virtual assistance-based lifestyle intervention was effective, cost-effective and acceptable in reducing risk factors for diabetes in young employees in the information technology industry, and is potentially scalable.

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Introduction

Trials, mostly targeting middle-aged adults with impaired glycaemic status, have shown that intensive lifestyle modification can reduce conversion from prediabetes to Type 2 diabetes by almost 50% [1,2]; however, these trials were expensive and labour intensive [3,4]. In recent years 'mHealth' and 'eHealth' have emerged as encouraging tools for health promotion [5,6]. We investigated the effectiveness of mobile phone and e-mail (virtual assistance)-based lifestyle intervention in reducing Type 2 diabetes risk factors in adults with normoglycaemia at high risk of developing diabetes. We targeted employees in the information technology (IT) industry because they tend to be young technology-savvy adults with a sedentary workstyle, erratic eating habits and high stress levels [7].

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Methods

LIMIT (LIfestyle Modification in IT) was a randomized controlled trial conducted during 2012–2015 in two multinational IT industries in Pune (India).

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What's new?

- We investigated the effectiveness of virtual assistance in reducing Type 2 diabetes risk factors in young, technology-literate, adults with normoglycaemia who were at high risk of developing diabetes.
- A combination of mobile phone messages (text) and e-mails (graphics) was used to promote healthy lifestyle behaviours.
- The intervention was effective, cost-effective and acceptable in reducing overweight/obesity and other cardiometabolic risk factors at 1 year.
- Those who achieved a greater number of lifestyle goals experienced greater risk reduction.
- This approach is potentially scalable and holds promise for low- and middle-income countries.

Participants with ≥3 risk factors (family history of cardiometabolic disease, overweight/obesity, high blood pressure, impaired fasting glucose, hypertriglyceridaemia, high LDL cholesterol and low HDL cholesterol) were included. We excluded those with diabetes, hypertension or lipid abnormalities requiring treatment, major illness and disability restricting physical activity, as well as pregnant women. The study protocol was approved by the Ethics Committee of the King Edward Memorial Hospital Research Centre, and informed written consent was obtained from all participants.

Height, weight, waist circumference and blood pressure (digital monitor) were measured using standardized methods. Plasma glucose, triglyceride, total cholesterol and HDL cholesterol levels were measured using standard kits (coefficient of variation <4%). A pretested questionnaire was used to record demographic details, medical and family history, lifestyle recall (diet, physical activity and substance use) and awareness of diabetes [8].

Before randomization, all participants attended a 1-h group session on lifestyle modification. Overweight/obese participants were set a target to lose a minimum of 5% of their baseline weight [1]. To achieve this, four lifestyle modification goals were identified based on baseline observations (Table 1) and standard guidelines [9]. Written information on diet and physical activity was distributed at the session.

A research assistant not involved in data analysis allocated eligible participants to an intervention or a control group (1:1) using a centrally generated computer randomization scheme [10]. Participants and field staff could not be masked to group allocation but the laboratory staff and statisticians were masked until the end of analysis.

The intervention group received information on lifestyle modification through mobile phone messages (Appendix S1A) and e-mails (Appendix S1B) for 1 year. After a survey of participants' preferences, three mobile phone messages and two e-mails were sent per week between 1000–1300 h; no message was repeated. E-mails contained info-graphics [11]. Participants in the intervention group had additional support through a website (requiring login) and a Facebook page (closed group); they were advised not to share the messages, e-mails or the details of the website and Facebook page to prevent contamination. Of a total of 150 mobile phone messages and 100 e-mails sent, one-tenth requested a reply (Appendix S1A and B). Adherence was calculated based on the response to these requests. We reassessed all the participants every 3 months for anthropometry and blood pressure. Biochemistry, lifestyle recall, diabetes awareness and acceptability of the intervention were measured at 1 year. Adverse events and treatment of intercurrent illnesses were systematically recorded [12] at each follow-up visit.

Outcomes

The primary outcome was prevalence of overweight/obesity (BMI ≥25 kg/m^2). Secondary outcomes included change in weight, waist circumference, blood pressure, glucose, lipids, lifestyle choices (physical activity, frequencies of calorie-dense and fibre-rich foods, smoking), diabetes awareness score, acceptability and cost-effectiveness of the intervention.

We calculated the incremental cost to treat/prevent one case of overweight/obesity within the 1-year trial period [(intervention costs–control costs)*number-needed-to-treat]; we considered only direct medical costs (including research costs).

Statistical analysis

To detect a relative reduction of 25% in prevalence of overweight/obesity between the intervention and control groups (1:1) at 1 year at 5% significance and 80% power, and assuming a drop-out rate of 25%, we required 132 individuals in each group. Analysis was carried out by intention to treat, including all randomized participants. Participants who were lost to follow-up were analysed using the last observation carried forward method.

Comparisons between baseline and subsequent measurements were made using a paired *t*-test. Differences between the two groups were assessed by ANOVA. McNemar test was used to compare paired proportions. The number-needed-to-treat was calculated as the inverse of the absolute risk reduction. Analysis was carried out using SPSS (version 16).

Results

We screened 437 employees for risk factors and identified 265 (60.6%) who had ≥3 risk factors and were randomized. They had a mean age of 36.2 ± 8.0 years and 72.5% were

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Table 1 Comparison between intervention and control group

	Intervention group (n= 133, 74.4% men)			Control group (n= 132, 70.5% men)			P (for difference in Δ between groups)
	Baseline	1 year	Δ (95% CI)	Baseline	1 year	Δ (95% CI)	
Demographics							
Age, years	36.8 (7.2)			35.7 (8.1)			—
Family history	63 (47.4)			68 (51.5)			—
Anthropometry							
Weight, kg	74.2 (10.1)	73.2 (10.2)	−1.0 (−1.5, −0.5)	75.4 (12.8)	76.1 (13.3)	0.7 (0.3, 1.2)	<0.001
BMI, kg/m^2	27.0 (3.2)	26.6 (3.2)	−0.4 (−0.6, −0.2)	27.3(3.5)	27.6 (3.7)	0.3 (0.1, 0.4)	<0.001
BMI ≥25 kg/m^2, n (%)	104 (78.2)	96 (72.2)	−6.0 (−11.3, −0.7)	101 (76.5)	110 (83.3)	6.8 (1.7, 11.8)	0.020
Waist circumference, cm	95.6 (7.3)	93.9 (7.5)	−1.7 (−2.3, −1.2)	96.1 (9.3)	96.6 (9.6)	0.5 (0.1, 0.9)	<0.001
Blood pressure, mmHg							
Systolic	113.2 (11.7)	113.1 (13.4)	−0.1 (−1.9, 1.8)	113.3 (11.7)	114.1 (12.7)	0.9 (−0.8, 2.5)	0.452
Diastolic	77.6 (8.9)	76.2 (9.9)	−1.4 (−2.8, −0.1)	76.9 (8.9)	76.7 (9.9)	−0.3 (−1.5, 1.0)	0.191
Biochemistry							
Fasting plasma glucose, mmol/l	4.12 (0.54)	4.31 (0.52)	0.20 (0.12, 0.28)	4.11 (0.52)	4.44 (0.57)	0.33 (0.25, 0.42)	0.022
Median (IQR) triglycerides, mmol/l	1.22 (0.95–1.77)	1.31 (0.95–1.81)	0.07 (−0.002, 0.15)	1.13 (0.84–1.63)	1.24 (0.88–1.65)	0.12 (0.02, 0.23)	0.467
Total cholesterol, mmol/l	4.65 (0.93)	4.48 (0.88)	−0.17 (−0.25, −0.10)	4.55 (0.78)	4.53 (0.79)	−0.03 (−0.10, 0.05)	0.006
LDL cholesterol, mmol/l	3.00 (0.81)	2.81 (0.76)	−0.19 (−0.26, −0.12)	2.92 (0.63)	2.85 (0.64)	−0.08 (−0.15, −0.01)	0.023
Median (IQR) HDL cholesterol, mmol/l	0.98 (0.88–1.10)	0.96 (0.88–1.09)	−0.02 (−0.03, 0.01)	0.98 (0.85–1.11)	0.98 (0.85–1.11)	−0.01 (−0.02, 0.01)	0.401
Lifestyle goals, n (%)							
Exercise: ≥150min/week	30 (22.6)	57 (42.9)	20.3 (11.8, 28.7)	26 (19.7)	29 (22.0)	2.3 (−4.2, 8.8)	<0.001
Intake of fibre-rich foods: ≥8 servings/week	19 (14.3)	32 (24.1)	9.8 (3.6, 16.0)	20 (15.2)	20 (15.2)	0.0 (−6.7, 6.7)	0.140
Intake of calorie-dense foods: ≤4 servings/week	18 (13.5)	39 (29.3)	17.1 (9.6, 24.5)	10 (7.6)	14 (10.6)	3.0 (−1.9, 7.9)	0.140
Awareness score ≥75%	4 (3.0)	41 (30.8)	27.8 (19.5, 36.2)	9 (6.8)	13 (9.8)	3.0 (−1.3, 7.4)	<0.001
Smokers	15 (11.3)	11 (8.2)	−3.1 (−6.7, 0.6)	22 (16.8)	22 (16.8)	0 (−2.8, 2.8)	0.600

IQR, interquartile range.
Numbers are mean (SD) unless otherwise indicated. There was no difference in baseline characteristics between the two groups.

men. Control and intervention groups were similar in baseline characteristics (Table 1).

There were a total of 62 drop-outs [intervention group: 28 (21.1%), control group: 34 (25.8%); *P* for difference between the groups =0.366 (Fig. 1)]; job changes, travel and work schedules were the most common reasons. Those who were lost to follow-up were no different from those who continued in the trial with regard to their baseline characteristics (demography, anthropometry and biochemistry).

After 1 year, the number of overweight/obese participants decreased from 104 (78.2%) to 96 (72.2%) in the intervention group (P=0.021), while it increased from 101 (76.5%) to 110 (83.3%) in the control group (P=0.004); risk difference 11.2% (95% CI 1.2–21.1; P=0.042). The number-needed-to-treat/prevent one case of overweight-obesity in 1 year was 9 (95% CI 5–82).

At 6 months, the intervention group had significantly greater reductions in weight [-1.1 (95% CI -1.5, -0.7) vs 0.5 (95% CI 0.2, 0.9) kg; P<0.001], waist circumference [-1.5 (95% CI -1.9, -1.1) vs 0.5 (95% CI 0.2, 0.7) cm; P<0.001], systolic blood pressure [-1.9 (95% CI -3.2, -0.6) vs 0.7 (95% CI -0.9, 2.3) mmHg; P=0.012], and diastolic blood pressure [-1.3 (95% CI -2.3, -0.3) vs 0.4 (95% CI -0.8, 1.5) mmHg, P=0.033] compared with the control group. Improvements were sustained at 1 year with the exception of systolic and diastolic blood pressure (Table 1 and Appendix S1C and D). The intervention group had significantly greater reductions in total and LDL cholesterol, and a lower rise in glucose level than the control group at 1 year (Table 1).

At 1 year, participants in the intervention group achieved a greater number of lifestyle goals compared with those in the control group. Those who achieved a greater number of

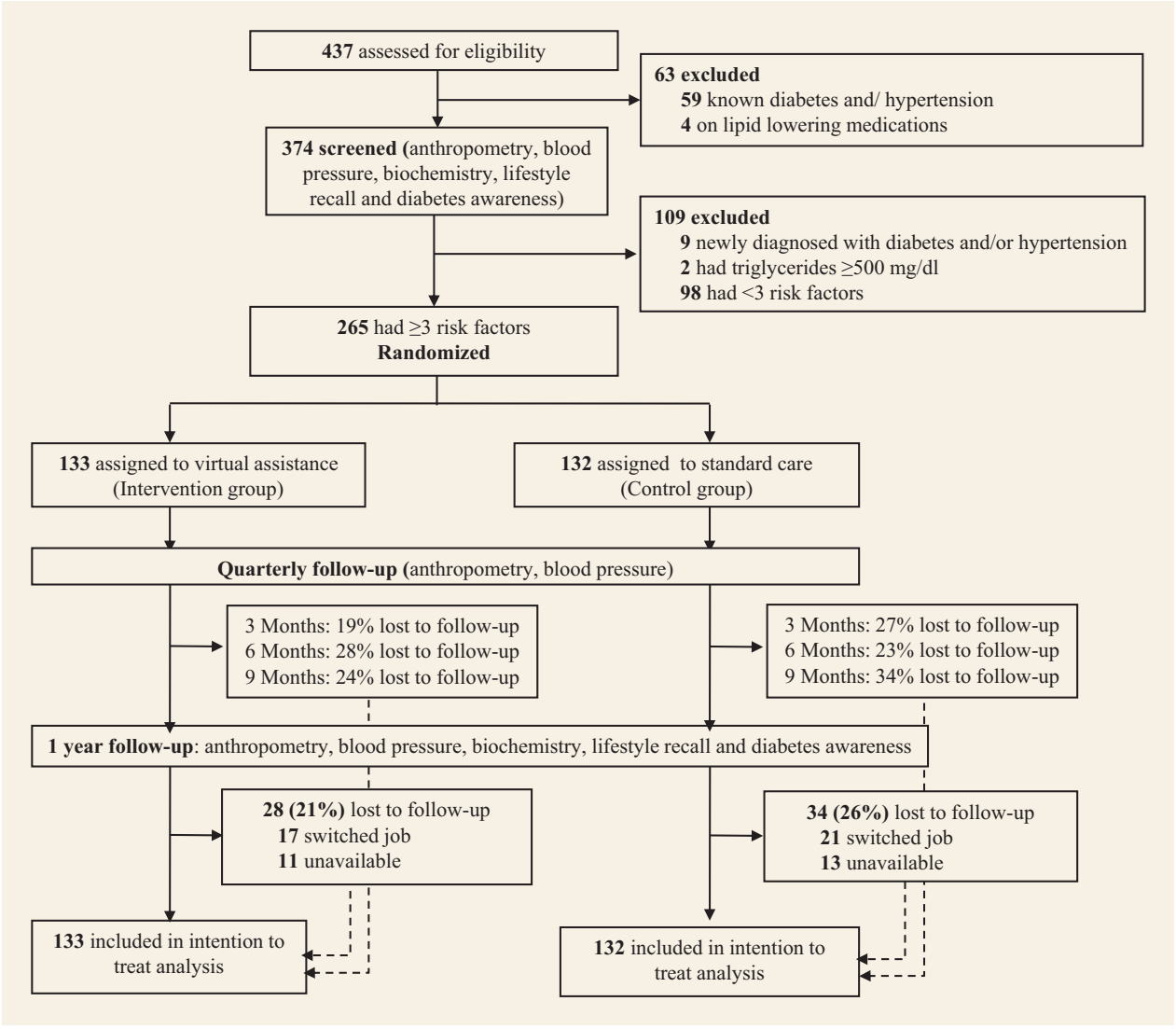

FIGURE 1 Trial profile.

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lifestyle goals had a greater reduction in weight (Appendix S1E).

Adherence was 84.5% at 6 months (mobile messages: 89.0%, e-mails: 80.0%) and 74.5% at 1 year (mobile messages: 78.0%, e-mails: 71.0%). The average e-mail opening rate was 93% and 88% at 6 months and 1 year, respectively. There were 103 reports of adverse events (intervention group=54, control group=49; P=0.562) during the study period; none of them were thought to be attributable to the intervention.

The intervention was well received; 98% of participants opted for a continuation of the virtual assistance, while 96% would recommend it to family and friends.

Over 1 year, the direct medical cost of the intervention was INR 2216 (£23.30) per participant in the control group, and INR 3401 (£35.80) in the intervention group (Appendix S1F). Thus the incremental cost of treating/preventing one case of overweight/obesity in 1 year was INR 10665 (£112.30).

Discussion

The findings of the present study show a high burden of risk factors for Type 2 diabetes and cardiovascular disease in young Indian employees in the IT industry. Virtual assistance-based lifestyle intervention in these high-risk employees reduced the prevalence of overweight/obesity significantly, and led to improvements in waist circumference, and total and LDL cholesterol levels at 1 year. Those who achieved a greater number of lifestyle goals experienced a greater risk reduction. Virtual assistance through mobile messages and e-mails was an acceptable method to deliver advice.

The observed weight reduction, although small, was similar to that reported in other pragmatic lifestyle interventions [13]. In the Diabetes Prevention Programme, every 1 kg of weight loss was associated with a 16% reduction in the risk of incident diabetes [14]. On this background, the observed weight reduction (~1 kg) may be meaningful, particularly at population level. Our intervention also reduced other cardiovascular risk factors. The beneficial effects persisted at 1 year of intervention duration. The only Indian trial studying effectiveness of mobile phone messaging on prevention of diabetes [15] reported lower cumulative incidence of Type 2 diabetes, but no significant effect on weight. Similarly to the present findings, mobile phone messaging was found to be an acceptable method to deliver lifestyle advice.

The cost in the present study was relatively low for treating/preventing one case of overweight/obesity in a high-risk population in 1 year, and is likely to be lower in non-research population settings. Other advantages of our approach include the non-invasive nature of the intervention, relative ease of administration, and low numbers of staff required for delivery.

Given the rapid growth of the IT sector in India and the high burden of risk factors in these professionals, lifestyle advice through virtual assistance may be an efficient and potentially scalable intervention in this technology-literate population. Such interventions may also be applicable to other workplace settings in promoting healthy lifestyle. The number of mobile phone and internet subscribers in urban as well as rural parts of India is increasing exponentially [16], including amongst children [17], and virtual assistance may be useful for health promotion generally. This will also apply to other low- and middle-income countries [18], where mobile technology is making rapid inroads.

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Competing interests

None declared.

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References

1 Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P *et al*. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001; **344**: 1343–1350.
2 Ahmad LA, Crandall JP. Type 2 Diabetes Prevention: A Review. *Clinical Diabetes* 2010; **28**: 53–59.
3 Hernan WH, Brandle M, Zhang P, Williamson DF, Matulik MJ, Ratner RE *et al*. Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes Care* 2003; **26**: 36–47.
4 Ramachandran A, Snehalatha C, Yamuna A, Mary S, Ping Z. Cost-effectiveness of the interventions in the primary prevention of diabetes among Asian Indians: within-trial results of the Indian Diabetes Prevention Programme (IDPP). *Diabetes Care* 2007; **30**: 2548–2552.
5 Vodopivec-Jamsek V, de Jongh T, Gurol-Urganci I, Atun R, Car J. Mobile phone messaging for preventive health care. *Cochrane Database Syst Rev* 2012; **12**: CD007457.
6 World Health Organization (WHO). WHO Global Observatory for eHealth New horizons for health through mobile technologies. Geneva: World Health Organization, 2011.

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7 Indian Council for Research on International Economic Relations. Lifestyle diseases hit India's IT workers. September 2007. Available at http://test.icrier.org/page.asp?MenuID=182&SubCatId=187&SubSubCatId=398 Last accessed 25 October 2014.
8 Limaye TY, Wagle SS, Kumaran K, Joglekar CV, Nanivadekar AS, Yajnik CS. Lack of knowledge about diabetes in Pune - the city of knowledge! *Int J Diabetes Dev Ctries* 2016; **36**: 263.
9 National Institute for Health and Clinical Excellence (NICE). Preventing type 2 diabetes: risk identification and interventions for individuals at high risk. NICE public health guidance 38. July 2012. Available at http://www.nice.org.uk/guidance/ph38 Last accessed 31 July 2012.
10 Dallal GE. Randomization Plans. August 2007. Available at http://www.randomization.com Last accessed 13 April 2012.
11 Smiciklas M. *The power of infographics*. Wiegand G. (ed.). Pearson Education, Inc.: Upper Saddle River, NJ, 2012; 7–16.
12 Central drugs standard control organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Good clinical practice guidelines. April 1996. Available at http://rgcb.res.in/wp-content/uploads/2014/07/good-clinical-practice-guideline.pdf Last accessed 26 March 2015.
13 Dunkley AJ, Bodicoat DH, Greaves CJ, Russell C, Yates T, Davies MJ *et al*. Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations: a systematic review and meta-analysis. *Diabetes Care* 2014; **37**: 922–933.
14 Hamman RF, Wing RR, Edelstein SL, Lachin JM, Bray GA, Delahanty L *et al*. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care* 2006; **29**: 2102–2107.
15 Ramachandran A, Snehalatha C, Ram J, Selvam S, Simon M, Nanditha A *et al*. Effectiveness of mobile phone messaging in prevention of type 2 diabetes by lifestyle modification in men in India: a prospective, parallel-group, randomised controlled trial. *Lancet Diabetes Endocrinol* 2013; **1**: 191–198.
16 Telecom Regulatory Authority of India. Highlights on telecom subscription data as of 31 May 2014. Available at http://trai.gov.in/WriteReadData/WhatsNew/Documents/PR-TSD-May,%2014.pdf Last accessed 18 October 2014.
17 Groupe Speciale Mobile (GSM) Association and the Mobile Society Research Institute. Children's use of mobile phones. An international comparison 2013, Executive Summary. 2014. Available at http://www.gsma.com/publicpolicy/wp-content/uploads/2014/02/GSMA-NTT-DOCOMO-Childrens-Report_ExecSummary_RR_-Web1.pdf Last accessed 30 October 2014.
18 International Telecommunication Union, ICT facts and figures: The world in 2015, May 2015. Available at https://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2015.pdf Last accessed 8 September 2015.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1A. Sample messages.
Appendix S1B. Sample emails.
Appendix S1C. Change in body weight at serial follow-up visits: intervention group lost significantly more weight during the trial, starting 3 months after intervention.
Appendix S1D. Change in anthropometric measurements, blood pressure and biochemical measurements (mean z-scores with 95% CI: in comparison with the control group).
Appendix S1E. Number of lifestyle goals achieved and corresponding mean weight change in participants by allocation group at 1 year.
Appendix S1F. Cost analysis of virtual assistance-based lifestyle intervention.

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