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Original research

## The effect of text message support on diabetes self-management in developing countries – A randomised trial



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## ABSTRACT

**Objective:** mHealth interventions have the potential to facilitate self-management. This TEXT4DSM study implemented a mobile phone intervention in existing diabetes programmes in three low- and middle-income countries (Democratic Republic of Congo, Cambodia, and the Philippines).

**Research design and methods:** Sub-studies with a similar randomised controlled trial design were conducted in three different countries. Each sub-study included 480 adults with diabetes. Subjects were randomised to receive either routine care or routine care plus text message self-management support. The primary outcome was the difference in the proportion of subjects with well-controlled diabetes after 2 years.

**Results:** Baseline and 2-year HbA1c measurements were available for 781 individuals. After 2 years, the proportion of subjects with controlled HbA1c was 2.8% higher in the intervention group than in the control group (difference not statistically significant). In the logistic regression model, the odds ratio for having controlled diabetes after the intervention was 1.1, after adjusting for baseline HbA1c level, sex, receiving insulin treatment, and participating in the routine programme. The HbA1c dynamics over time differed between programmes; the number of people with controlled diabetes tended to increase in DR Congo and decrease in Cambodia.

**Conclusion:** This study was the first to test the same mHealth intervention in different countries. The finding that text messages did not show an additional effect on diabetes control implied that expectations about mHealth should be cautious. The degree of coverage, the quality of the routine programme, and the progression of disease can interfere with the expected impact.

Trial registration: ISRCTN registry (86247213).

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## Introduction

Global attempts to increase access to diabetes care in low-income countries (LICs), have shown that the quality of diabetes care is important, and it should comprise dimensions of chronic care models, including self-management. Self-management is recognized as an essential component of diabetes care [1–3]. Diabetes Self-Management Education (DSME) and Diabetes

**Abbreviations:** DSME, Diabetes Self-Management Education; DSMS, Diabetes Self-Management Support; DR of Congo, Democratic Republic of Congo; LICs, Low Income Countries; ITT, Intention to Treat.

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Self-Management Support (DSMS) are activities to assist people in sustaining self-management behaviours. These complementary elements were shown to have beneficial effects [4,5]. However, it remains a challenge to implement these chronic care elements into health systems in LICs. Some previous initiatives [6–8] have focused on education, but few have focused on supporting broader goals, such as realizing behaviour changes or developing coping skills.

Diabetes self-management support interventions include a combination of tools designed to reach patients, including brochures, phone calls, and websites. Interventions that use mobile technology (mHealth) have the potential of facilitating self-management, education, and support [9]. mHealth applications have been limited in LICs, and they have had mixed effects on diabetes control [10–13]. However, most studies have been small and of limited quality. Often, the theory underlying the intervention was not elaborated. Knowledge from behavioural sciences that can explain the pathway from knowledge and perception to intentions and actual behaviour – such as the theory of planned behaviour – has not been widely included in study designs or data evaluations. This lack of theory limits our understanding of the added value of mHealth interventions in self-management support and diabetes care programmes in LICs.

This study, called the TEXT4DSM study, implemented a mobile phone DSMS intervention in three diabetes programmes that existed in the Democratic Republic of (DR) Congo, Cambodia, and the Philippines [14]. The overall aims of the study were to evaluate the effectiveness of the intervention in each country and to assess the processes and contextual factors that influenced the implementation. Previous reports analysed the health care context in the three settings and the process of implementation [15,16]. The present study assessed the effect of the intervention after 2 years on health outcomes and on intermediate outcomes. The primary outcome was the change in the proportion of subjects with a HbA1c below 7.0% (53 mmol/mol) after 2 years.

## Methods

### Study design

This study consisted of three sub-studies in three countries. Each sub-study was designed as a two-arm, randomised controlled trial (RCT). Each sub-study included 480 adults with diabetes (type 2 or 1) that were currently participating in an existing DSME programme. Participants were randomly allocated to either self-management education, as provided by the existing programme (DSME-only; control group), or to self-management education plus a mobile phone for self-management support (DSME + DSMS; intervention group) [14]. Participants in both arms were assessed at baseline, at one year, and at two years after inclusion. The primary outcome measure was the change in the percentage of subjects with well-controlled HbA1c levels after 2 years. Outcomes were compared between the intervention and control groups. A secondary outcome measure was the change in HbA1c levels after 2 years. Again, the intervention and control groups were compared. The study design is shown in Fig. 1 (in the web annex).

### Ethics approval

Medical ethics approval for this study was obtained from the Institutional Review Board of the Institute of Tropical Medicine, Antwerp (11245776); the Medical Ethics Committee of the Universitair Ziekenhuis, Antwerpen (B30020111924); the National Ethics Committee for Health Research in Cambodia (207 NECHR); the University of Kinshasa in the DR Congo (ESP/CE/050/11); and

the Veterans Memorial Medical Centre in the Philippines (VMMC-2011-012). The project was reviewed by the Bridges Executive Committee.

### Study context and subjects

The studies took place within the 'Kin-réseau' programme in DR Congo, the 'MoPoTsyo' programme in Cambodia, and the First Line Diabetes Care (FiLDCare) project in the Philippines. Kin-réseau is a 40-year old network of faith-based primary care facilities in Kinshasa, which deliver diabetes care and education as part of their basic package. MoPoTsyo is a community-based peer educator network supported by a Non-Governmental Organisation (NGO), in which patients are recruited through community screening, receive biomedical care facilitated by the NGO, and receive self-management support in groups facilitated by a peer educator. In the FiLDCare project, trained health workers and Barangay (community) health workers provide diabetes education and support for patients with diabetes. Subjects were eligible for study participation, when they were  $\geq 18$  years old, had been diagnosed with diabetes, were registered in a centre participating in the study, and had received at least one session in the usual care programme during the preceding year.

### Routine programme: biomedical care and DSME

The biomedical care consisted of periodic consultations with a doctor (ranging from every 2 months in the Kin-réseau to every half year in MoPoTsyo), which included monitoring glycaemia and risk factors and prescribing medication. Educators provided ongoing DSME. In Kin-réseau, a nurse scheduled weekly DSME sessions, with groups of about 100 patients. In MoPoTsyo, peer educators scheduled monthly DSME sessions, typically with groups of 60 patients. In FiLDCare, DSME sessions were scheduled on a regular, but not fixed basis, with groups of about 8 patients [15]. Educators used posters and booklets to convey their message, both in group sessions and in individual contacts. In preparation for the study, the DSME programme was optimised to a minimum standard, which comprised messages for about nine dimensions of diabetes self-management. The messages were related to diabetes self-care and self-management; they were based on literature, professional standards, and consultations with diabetes experts [17–19]. The nine dimensions were: 1) explanation of diabetes disease processes; 2) healthy eating; 3) physical activity; 4) monitoring; 5) medications; 6) foot care; 7) tobacco and alcohol control; 8) patient-held records; and 9) problem-solving by and empowerment of patients.

### The DSME plus DSMS intervention

Each participant, in both control and intervention groups, was provided with a mobile phone at inclusion in the study. Contracts were negotiated with a national phone provider for buying new phones and SIM cards for all participants and for sending messages. Patients were encouraged to use the phone, for instance, to ask for advice or simply to contact other people, including fellow patients, educators, and providers. Ongoing contact with the diabetes educator provided the opportunity for patients to engage actively and to discuss the potential implementation of behaviour changes. Although participants in the control group received a mobile phone, they did not receive project-initiated phone messages.

Patients in the intervention group received DSMS through automated Short Message Services (SMS) on the mobile phone. The messages were sent with the open access software, Frontline [20], in Kin-réseau and MoPoTsyo, and with the internet-based

application, 'Chikka', in FiLDCare [21]. Messages for the DSMS were developed according to the nine dimensions of DSME. The overall protocol included a guideline about the content of messages and the underlying principles of the behaviour theory of change. The administrators of each of the three programmes developed their own protocol on the development and delivery of DSMS. These protocols took into account the local features of the organisation and context of text messaging, including the contract with the local telephone providers and the cost of sending SMS messages. These protocols specified that messages should be sent 5 times per week in Kin-réseau, 6 times per week in MoPoTsyo, and 2 times per week in FiLDCare. The message contents were developed by a team in each country, which comprised the project manager, assistant programme manager, an educator, and a general doctor with additional diabetes training.

The implementation manager was responsible for sending SMS messages and for following-up any problems with coverage for the intervention. Most problems were related to technological barriers (with the phone, the subscription, or the network), contextual changes (new phone providers and people switching phone numbers), or problematic participant behaviour (people not reading their messages). Subscriptions were renewed, phone numbers adjusted and, when no other option was possible, new phones were provided. In MoPoTsyo, the manager implemented two innovations in the intervention in the 2nd year. The first was the use of voice messaging instead of SMS, due to limitations in using Khmer script; the second was the targeting of one quarter of all messages to specific groups, for instance to obese patients. The 1-year process evaluation showed that the average number of SMS messages sent to participants was 15.7 per month in Kin-réseau, 24.7 in MoPoTsyo, and 7.3 in FiLDCare, with a gradual decline over time. The decline was explained by a delay in the development of new messages [16].

#### *Theoretical intervention model*

The theoretical framework underlying the DSMS intervention was based on the hypothesis that the messages would affect the knowledge and perceptions of patients, and this input would lead, in turn, to a change in self-management behaviour and in the utilisation of care by individual patients. The theoretical pathway to changing behaviour was largely based on the theory of planned behaviour. This theory explains how beliefs (behavioural, normative, and control beliefs) shape individual attitudes, the subjective norm, and the perceived behavioural control, which together shape the intention, and ultimately, the execution of a particular behaviour [22,23]. The theory has been largely used to understand observed behaviour patterns, but it was also recommended as a tool in designing interventions [24]. Messages were intended to target the behavioural, normative, and control beliefs attached to each of the diabetes self-management behaviours [24,25]. The self-management behaviours targeted were generic, but the beliefs that were addressed were specific for each context. For example, some of the messages sent were: "Keeping diabetes under control will protect your foot" (targeting behavioural beliefs), "A patient with diabetes should avoid walking barefoot" (addressing normative beliefs), and "We are trying to understand and learn how to manage diabetes on our own" (addressing control beliefs). Changing behavioural beliefs was expected to contribute to behavioural changes, when there was an opportunity and no obstacles. Changes in self-management and in the utilisation of care – which can be considered intermediate outcomes – were expected to lead to improved health outcomes over the long term (webannex, Fig. 2). The framework also indicated other factors that might impact or interfere with these pathways, such as personal or biomedical

characteristics, the content of the routine programme, and the environment.

#### *Recruitment*

Patients and staff from the participating centres in each programme were informed about the study, and patients were invited to participate. The randomisation system used a 4 × 4 randomised block design, with the participant as the unit of randomisation. Study code numbers and randomisation envelopes were prepared prior to enrolment. After informed consent, participants were allocated to either the control or intervention trial arm. Randomisation was blinded, but the nature of the intervention informed participants about the arm they were assigned to, and educators typically learned this information through the participants.

#### *Measurements and measures*

We report on personal characteristics (sex, age, education, age of onset, time since diagnosis, travel distance to educator and doctor); on health outcomes (HbA1c, BMI, waist circumference, waist-hip ratio, blood pressure, presence of foot wounds); on the routine programme (diabetes treatment, antihypertensive treatment, an adapted version of the Patient Assessment of Chronic Illness Care score [PACICc]) [26]; on utilisation of care (contacts with educator, health care expenditure); on patient knowledge and perceptions (diabetes knowledge, feeling of control, positive and negative attitudes); and on self-management behaviour (self-monitoring glucose levels). The details on data collection were reported elsewhere [14].

Data were collected from 2012/2013 to 2014/15; they included a face-to-face interview with a predefined questionnaire, a physical examination, and a blood panel [14]. For each participant, data were collected at baseline, year 1, and year 2. Additional efforts were made to contact participants that were not present for data collection, to retrieve participants, or to obtain information about the reasons for failing to follow-up. Those reasons were recorded in a database. Patients that died, stopped the study due to diabetes-related morbidity, migrated, declined to continue in the study, or failed to follow up for unknown reasons were not included in the analysis.

#### *Sample size*

The primary measure for calculating the sample size was the difference in the proportion of patients with well-controlled HbA1c levels (defined as HbA1c < 7.0% [53 mmol/mol]) after 2 years. The required sample size was 240 participants in each arm, in each country. This calculation was based on the following assumptions: 1) 60% of the participants had well-controlled HbA1c levels at the start; 2) a difference of 15% between the intervention and control groups was relevant, with a 2-sided significance level of 5% and a power of 80%; 3) 10% of patients would drop out over the study period [14].

#### *Analysis*

Analyses of quantitative data were performed with Stata version 11. A p-value < 0.05 was considered statistically significant for all tests. Continuous variables were tested for normality, and non-normal distributions were categorised. Descriptive analyses were performed for all variables. Unadjusted comparisons between study groups were performed with *T*-tests (for continuous variables), the Kruskal-Wallis test (for comparisons of medians), or Chi-square tests (for discrete variables). Data were analysed for confounding factors and interactions in multivariate regression

analyses. We considered potential confounding effects from the following variables: HbA1c level at baseline (<7.0% vs. ≥7.0%); sex; education level (primary or lower levels vs. secondary or higher levels); age (<45, 45–64, >64 years); time since diagnosis (<2, 2–4, 5–9, or >10 years); walking distance from the educator (≤15 vs. >15 min); obesity at baseline (body mass index [BMI] >30); unfavourable waist circumference at baseline (>80 cm for females and >94 cm for males in DR Congo; >90 cm for men in Cambodia/Philippines [27]); insulin treatment at baseline; and the number of SMS that an individual remembered having received in the prior month (≥10 vs. <10). These variables were selected based on earlier evidence about determinants of HbA1c [28], our theoretical framework, and the significance of a factor based on a bivariate analyses of our own dataset ( $p < 0.10$ ). We started with a simple model, which only included outcome (HbA1c status at the study end), intervention, and country (considered to be a dummy variable). We added the other variables one by one, and each variable was only retained in the model when its presence altered the OR substantially and when the difference between the two models was significant ( $p$ -value of the likelihood ratio test <0.05). After deciding which variables to retain in the model, we checked these variables for interactions.

In addition to a multivariate logistic regression analysis, we analysed the change in HbA1c levels over time with longitudinal regression models. Hierarchical models were used to assess the influence of educator characteristics on the effects. We performed two secondary outcome analyses. The first analysis determined the difference between the intervention and control groups in the percentage change of individuals with well-controlled HbA1c, over the 2-year study period (see [webannex, Fig. 1](#)). The second analysis determined the individual change for each patient over 2 years. Participant HbA1c levels were evaluated at baseline and after 2 years. HbA1c levels were categorised as follows: <7.0% (53 mmol/mol); 7.0–7.9% (53–63 mmol/mol); 8.0–8.9% (64–74 mmol/mol); or >9.0% (75 mmol/mol). Participants that remained in the same category after 2 years were classified as 'stable'. Participants that moved up one or more categories were classified as 'deteriorating'. Participants that moved down one or more categories were classified as 'improving'. We analysed the impact of the intervention with regression analyses.

We also analysed the effect of the intervention on other, secondary outcomes and intermediate outcome variables, as indicated in the theoretical framework. Other health outcomes analysed included changes in BMI, waist circumference, waist-hip ratio, systolic and diastolic blood pressure, and the presence of foot wounds. Intermediate outcome variables were related to: 1) the utilisation of care (change in the number of contacts with the educator over the past year; direct medical and non-medical health expenditures); 2) participant knowledge and perceptions (changes in the number of correct answers on the diabetes knowledge test; feeling of control and attitude towards diabetes); and 3) self-management

behaviour (self-monitoring). To capture changes in the routine programme, we also analysed changes in medication regimens and in the adapted PACICc. We performed multivariate regression analyses to check the influence of potential confounding factors on the most relevant intermediate outcome variables (knowledge, positive and negative attitudes, feelings of control, self-monitoring, and contacts with the educator); we considered the same potential confounders as those analysed for the primary outcome.

We performed all analyses twice. The first analysis was performed at the aggregate level, which included all participants, with the country included as a dummy variable. The second analysis was performed at the programme level, which included the participants of each country separately.

## Results

### Participants and baseline characteristics

The study included 781 participants with both baseline and 2-year follow-up HbA1c measurements. Of these, 401 were allocated to the intervention and 380 were allocated to the control group. These participants included 315 from Kin-réseau, 382 from MoPoTsyo, and 84 from FiLDCare ([webannex, Fig. 3](#)). The high loss to follow-up (LTFU) rate in FiLDCare was largely due to a discontinuation of the study in the largest of three field sites, which eliminated 317 participants. The participants in the two other field sites of FiLDCare had a LTFU rate comparable to those in Kin-réseau and MoPoTsyo. The LTFU rate due to death was larger in Kin-réseau (11%) than in the other programmes (3% and 1%). For 20 cases in DR Congo, the cause of death was recorded: 3 were directly caused by diabetes, and the other 17 were caused by various conditions, including cerebrovascular accidents, infectious diseases, and 'old age'. [Table 1](#) gives an overview of the differences in main characteristics between participants that completed the study and those in the LTFU group. These groups were significantly different in education levels (the LTFU group included more highly educated participants, due to differences in the FiLDCare programme). However, we found no other significant differences between groups. A previous study provided a full overview of the baseline characteristics of the study participants, the characteristics of care, physical outcomes, perceptions of care, and self-management [15]. A dataset that includes all participant data is available online ([webannex 2](#)).

### Effect of the intervention

After 2 years, an HbA1c <7.0% (53 mmol/mol), which was considered 'controlled diabetes', was achieved by 33.9% of subjects in the intervention group and 31.1% in the control group ([Table 1](#), aggregate analysis). This difference was not statistically significant ( $p = 0.39$ ).

**Table 1**  
Differences in baseline characteristics between participants that completed the study and those lost to follow-up ( $p < 0.05$ ).

	Overall (n 1471)		Kin-Réseau (n 506)		MoPoTsyo (n 484)		FiLDCare (n 481)	
	n in FU (781)	n LTFU (690)	n in FU (315)	n LTFU (191)	n in FU (382)	n LTFU (102)	n in FU (84)	n LTFU (397)
Sex (male),%	29	37	33	33	33	28	21	41
Age (mean ± sd)	58 ± 10	60 ± 10	59 ± 10	63 ± 11	55 ± 9	60 ± 12	59 ± 11	63 ± 9
Education primary only or less, %	50*	26	48	51	58	58	22*	7
Time since diagnosis, med (IQR)	4 (2–8)	6 (3–12)	6 (3–10)	7 (3–7)	4 (2–7)	4 (2–7)	4 (2–10)	7 (3–13)
Travel distance from educator (hour)	0.25	0.33	0.42	0.5	0.25	0.29	0.14	0.25
HbA1c at start (% mean ± sd)	8.2 ± 2.1	8.4 ± 2.3	8.8 ± 2.3	9.1 ± 2.4	7.5 ± 1.7	7.7 ± 2.0	8.6 ± 2.7	8.2 ± 2.3
% of people with a HbA1c <7.0% at start	35.1%	34.5%	23.2%	22.0%	44.5%	39.6%	38.1%	39.0%
Treatment with insulin, %	24%	22%	49%	59%	8%	11%	9%	6%

**Table 2**

Overview of the primary outcome measure: the proportion of subjects with controlled diabetes after 2 years; and the secondary outcome measure: the difference between intervention and control groups in changes from the start to the end of the study.

	Overall			Kin-réseau			MoPoTsyo			FiLDCare		
	DSME + DSMS (S)	DSME-only (E)	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S)	DSME-only (E)	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S)	DSME-only	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S)	DSME-only (E)	p, H0: $\Delta S = \Delta E$
% of people being controlled at end (<7.0%)	33.9%	31.2%	0.39	29.4%	21.9%	13.0%	35.4%	37.5%	0.66	44.2%	36.6%	48.0%
Change of % of people with controlled diabetes (p H0: $\Delta = 0$ )	-1.7%, p = 0.60	-3.6%, p = 0.28	0.09	+ 4.4%, p = 0.38	+ 0.6%, p = 0.89	0.04 <sup>*</sup>	-9.1%, p = 0.06	-7.1%, p = 0.17	0.47	+ 9.3%, p = 0.38	-4.9%, p = 0.65	0.43

In the final logistic regression model, the OR for achieving controlled diabetes after the intervention was 1.1 (95% CI 0.8–1.6). This OR was corrected for the diabetes control status at the start, sex, receiving insulin treatment, and participating in the routine programme. Testing for interactions between these variables did not change the predictive value of the model. There was no cluster effect at the educator level ([webannex, Table 1](#)).

We performed a longitudinal analysis to determine whether the intervention, the country, or the time (3 time points: at baseline, 1 year, and 2 years) influenced the chance of achieving controlled diabetes after 2 years. The best predictive temporal model had a random intercept and interaction terms for intervention, time, and country. The interaction analysis showed that the intervention time had a non-significant effect in all three programmes ([webannex, Table 2](#)).

#### Development of HbA1C over 2 years

The secondary outcome provided information about the development of HbA1C over time at the group level. We examined the change in the proportion of patients with controlled diabetes from baseline, and we compared the intervention group to the control group ([Table 2](#)). The results were different among the programmes. In Kin-réseau, the percent increase in subjects with controlled diabetes was significantly larger in the intervention than in the control group (4.4% vs. 0.6%,  $p = 0.04$ ). In MoPoTsyo, there was a decrease in subjects with controlled diabetes. In FiLDCare, diabetes control appeared to improve in the intervention group, but decrease in the control group; however, the remaining sample size was too small to demonstrate statistically significant differences.

The development of HbA1C in individual participants was evaluated by determining the different HbA1C categories (<7.0%; 7.0–7.9%; 8.0–8.9%; >9.0%) at the start and end of the study. We found that the majority of subjects did not change HbA1c categories over 2 years ([webannex, Fig. 4](#)). The proportion of subjects that remained in the same HbA1c category was larger in the control group (59.7%) than in the intervention group (50.6%). However, this difference was only significant in Kin-réseau (66.5% vs. 51.3%,  $p = 0.01$ ). The proportion of subjects that improved by at least one category was larger in the intervention group than in the control group (20.9% vs. 15.5%,  $p = 0.05$ ; aggregate analysis; [webannex, Table 3](#)).

In the logistic regression model, the OR for improving by at least one category after the intervention was 1.4 (0.9–2.0,  $p = 0.10$ ). This OR was corrected for the time since diagnosis, for remembering at least 50% of the DSMS, and for the country's routine programme. Testing for interactions between these variables did not improve the predictive value of the model; thus, interactions were ignored. Moreover, we did not observe a cluster effect at educator level ([webannex, Table 4](#)).

#### Other outcomes

The number of subjects with foot wounds decreased significantly more in the intervention group than in the control group. The intervention did not significantly alter the other health outcomes, even after controlling for potential confounding factors. For some secondary health outcomes, a significant change over time was observed, but the changes were similar for both intervention and control groups. For example, both groups showed increases in waist circumference and decreases in diastolic blood pressure, in all countries.

The intervention did not appear to have an effect on the intermediate outcome indicators, including patient knowledge, perceptions, and the utilisation of care ([Table 2](#)). Some indicators showed a change over time, but these changes were similar in both the intervention and control groups. For instance, all participants showed a drop in attendance to meetings with the educator in MoPoTsyo and FiLDCare. The negative attitude towards diabetes declined over time for all participants in Kin-réseau and FiLDCare. In MoPoTsyo, the number of subjects that self-monitored glucose levels significantly decreased in both the intervention and control groups.

[Table 2](#) also shows that some changes in diabetes management occurred in the routine programme, which affected both groups. In Kin-réseau, the number of participants that received insulin increased by 20% in both the intervention and control groups. In Kin-réseau and MoPoTsyo, the number of participants that received antihypertensive treatment increased in both groups, but the increase was greater in the intervention group than in the control group. In all programmes, the PACICc score declined ([Table 3](#)).

## Discussion

#### Summary of findings

The DSMS intervention in our study did not increase the number of subjects with controlled diabetes after 2 years. The multivariate regression analyses showed that the most important determinant for whether a subject had controlled diabetes after 2 years was starting with controlled diabetes at baseline. Consistent with the lack of a DSMS effect, the HbA1c analysis for individual participants showed that more than half of the participants remained in the same HbA1c category. However, the general tendencies in HbA1c dynamics over time were different between programmes. For all participants, the number with controlled diabetes increased in Kin-réseau, but decreased in MoPoTsyo. Moreover, the favourable development in Kin-réseau was significantly larger for the intervention group than for the control group.

There were no significant effects of the intervention on the intermediate outcomes or on other outcomes. For intermediate

**Table 3**  
Change in other health outcomes from the start to the end of the study, for intervention and control groups (pp = percentage point; headings refer to the theoretical framework shown in [web annex, Fig. 2](#)).

	Overall			Kin-réseau			MoPoTsyo			FildCare		
	DSME + DSMS (S) p(H0: start = end)	DSME-only (E) p(H0: start = end)	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S) p(H0: start = end)	DSME-only (E) p(H0: start = end)	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S) p(H0: start = end)	DSME-only (E) p(H0: start = end)	p, H0: $\Delta S = \Delta E$	DSME + DSMS (S) p(H0: start = end)	DSME-only (E) p(H0: start = end)	p, H0: $\Delta S = \Delta E$
<i>Other health outcomes</i>												
Change in BMI, mean $\pm$ sd	+0.0 $\pm$ 1.9, p = 0.92	+0.0 $\pm$ 2.4, p = 0.82	0.9	+0.3 $\pm$ 2.0, p = 0.85	+0.3 $\pm$ 2.7, p = 0.91	0.9	-0.1 $\pm$ 1.2, p = 0.70	-0.2 $\pm$ 1.6, p = 0.48	0.5	-0.1 $\pm$ 3.7, p = 0.87	+0.3 $\pm$ 4.1, p = 0.85	0.6
Change in waist circumference, mean $\pm$ sd	+3 $\pm$ 8, p = 0.00 <sup>*</sup>	+2 $\pm$ 8, p = 0.00 <sup>*</sup>	0.2	+4 $\pm$ 9, p = 0.00 <sup>*</sup>	+3 $\pm$ 9, p = 0.01 <sup>*</sup>	0.4	+2 $\pm$ 5, p = 0.07	+1 $\pm$ 5, p = 0.14	0.4	+6 $\pm$ 12, p = 0.02	+4 $\pm$ 15, p = 0.11	0.7
Change waist hip ratio, mean $\pm$ sd	0.00 $\pm$ 0.08, p = 0.39	0.00 $\pm$ 0.10, p = 0.22	0.7	0.00 $\pm$ 0.10	0.00 $\pm$ 0.13	0.9	+0.01 $\pm$ 0.05	+0.01 $\pm$ 0.05	0.5	+0.01 $\pm$ 0.08	+0.01 $\pm$ 0.12	1
Change in systolic blood pressure mean $\pm$ sd	+1 $\pm$ 24, p = 0.03 <sup>*</sup>	+2 $\pm$ 26, p = 0.00 <sup>*</sup>	0.6	0 $\pm$ 27, p = 0.99	+2 $\pm$ 30, p = 0.57	0.5	+5 $\pm$ 17, p = 0.01 <sup>*</sup>	+5 $\pm$ 18, p = 0.02 <sup>*</sup>	0.9	-9 $\pm$ 32, p = 0.14	-7 $\pm$ 33, p = 0.24	0.7
Change in diastolic blood pressure	-4 $\pm$ 14, p = 0.00 <sup>*</sup>	-3 $\pm$ 13, p = 0.00 <sup>*</sup>	0.5	-4 $\pm$ 16, p = 0.03 <sup>*</sup>	-3 $\pm$ 15, p = 0.04 <sup>*</sup>	0.8	-2 $\pm$ 10, p = 0.02 <sup>*</sup>	-2 $\pm$ 10, p = 0.01 <sup>*</sup>	0.9	-10 $\pm$ 19, p = 0.00 <sup>*</sup>	-5 $\pm$ 17, p = 0.11	0.2
Change in people with foot wound, pp	-3.5%, p = 0.02 <sup>*</sup>	-1.3%, p = 0.38	0.1	-9.0%, p = 0.01	-3.9%, p = 0.21	0.1	+0.5%, p = 0.65	+0.5%, p = 0.65	0.96	-2.3%, p = 0.64	0.0%, p = 1	0.33
<i>Utilisation of care</i>												
Change in number of contacts with educator (last year), median (IQR)	-2 (-9; +2), p = 0.00 <sup>*</sup>	-2 (-9; +2), p = 0.00 <sup>*</sup>	0.7	0 (-8; +6), p = 0.96	0 (-12; +4), p = 0.98	0.8	-4 (-9; 0), p = 0.00 <sup>*</sup>	-3 (-9; 0), p = 0.00 <sup>*</sup>	0.5	-2 (-8; 0), p = 0.00 <sup>*</sup>	-1 (-3; 0), p = 0.00 <sup>*</sup>	0.3
Change in direct health expenditure (USD), median (IQR)	+0.50 (-3.14; +4.31), p = 0.39	+0.25 (-3.81; +3.52), p = 0.04 <sup>*</sup>	0.2	-0.76 (-6.83; 7.02), p = 0.45	-2.01 (-8.17; +3.81), p = 0.01 <sup>*</sup>	0.2	+0.75 (-0.88; +3.02), p = 0.00 <sup>*</sup>	+0.75 (-0.63; +3.02), p = 0.06	0.8	-11.59 (-23.18; +44.83), p = 0.00 <sup>*</sup>	-11.59 (-42.88; +40.56), p = 0.00 <sup>*</sup>	0.5
Change in direct non-medical health expenditure, median (IQR)	0 (-3.27; +1.76), p = 0.39	0 (-3.27; +1.51), p = 0.01 <sup>*</sup>	0.9	-7.08 (-47.92; 3.22), p = 0.25	-6.29 (-38.06; 3.81), p = 0.87	0.7	0 (-1.26; +1.26), p = 0.43	0 (-1.26; +1.26), p = 0.01	0.6	0.00 (-8.11; +0.00) (n = 10)	-9.73 (-16.22; -8.81) (n = 7)	0.01 <sup>*</sup>
<i>Patient knowledge &amp; perceptions</i>												
Change in correct diab knowledge, mean	+0.3 $\pm$ 4.0, p = 0.16	+0.7 $\pm$ 4.3, p = 0.00 <sup>*</sup>	0.2	+0.3 $\pm$ 5.2, p = 0.53	+0.4 $\pm$ 4.3, p = 0.33	0.8	+1.0 $\pm$ 2.92, p = 0.00 <sup>*</sup>	+1.4 $\pm$ 2.98, p = 0.00 <sup>*</sup>	0.3	-2.7 $\pm$ 5.2, p = 0.00 <sup>*</sup>	-1.4 $\pm$ 6.1, p = 0.11 <sup>*</sup>	0.3
Change in feeling of control, mean	0.3 $\pm$ 3.2, p = 0.35	+0.2 $\pm$ 3.4, p = 0.46	0.8	-0.2 $\pm$ 3.4, p = 0.36	-0.7 $\pm$ 3.0, p = 0.06	0.3	0.3 $\pm$ 2.6, p = 0.31	+0.1 $\pm$ 2.9, p = 0.70	0.6	+2.0 $\pm$ 4.7, p = 0.00 <sup>*</sup>	+3.6 $\pm$ 4.5, p = 0.00 <sup>*</sup>	0.1
Change in positive attitude, mean	+0.3 $\pm$ 3.8, p = 0.11	0.0 $\pm$ 4.1, p = 0.94	0.2	+0.3 $\pm$ 4.2, p = 0.48	-0.5 $\pm$ 4.3, p = 0.14	0.1	-0.1 $\pm$ 3.1, p = 0.63	0 $\pm$ 3.5, p = 0.95	0.7	+2.5 $\pm$ 4.5, p = 0.00 <sup>*</sup>	1.8 $\pm$ 5.1, p = 0.02 <sup>*</sup>	0.5
Change in negative attitude, mean	-1.8 $\pm$ 6.4, p = 0.00 <sup>*</sup>	-1.3 $\pm$ 6.5, p = 0.00 <sup>*</sup>	0.3	-3.1 $\pm$ 6.3, p = 0.00 <sup>*</sup>	-2.1 $\pm$ 6.2, p = 0.00 <sup>*</sup>	0.2	+0.2 $\pm$ 5.6, p = 0.65	+0.7 $\pm$ 5.7, p = 0.13	0.4	-6.6 $\pm$ 6.5, p = 0.00 <sup>*</sup>	-7.1 $\pm$ 6.7, p = 0.00 <sup>*</sup>	0.8
<i>Self-management behaviour</i>												
Change in people self-monitoring, pp	-15.0%, p = 0.00 <sup>*</sup>	-10.4%, p = 0.00 <sup>*</sup>	0.1	+3.4%, p = 0.50	+5.5%, p = 0.27	0.4	-31.3%, p = 0.00 <sup>*</sup>	-28.3%, p = 0.00 <sup>*</sup>	0.51	-8.7%, p = 0.38	+9.2%, p = 0.38	0.94
<i>Indicators about the routine programme</i>												
Change in people on insulin treatment, pp	+7.4%, p = 0.01 <sup>*</sup>	+11.2%, p = 0.00 <sup>*</sup>	0.1	+20.3%, p = 0.00 <sup>*</sup>	+18.6%, p = 0.00 <sup>*</sup>	0.7	+0.2%, p = 0.93	+6.7, p = 0.06	0.00 <sup>*</sup>	1.4%, p = 0.84	+2.5%, p = 0.69	0.7
Change in people on antihypertensive treatment, pp	+15.8%, p = 0.00 <sup>*</sup>	+10.4%, p = 0.00 <sup>*</sup>	0.03 <sup>*</sup>	+22.2%, p = 0.00 <sup>*</sup>	+13.9%, p = 0.02 <sup>*</sup>	0.1	+16.3%, p = 0.00 <sup>*</sup>	+8.0%, p = 0.13	0.02 <sup>*</sup>	-10.5%, p = 0.29	+8.8%, p = 0.43	0.2
Change in PACIC, mean	-6.3 $\pm$ 12.8, p = 0.00 <sup>*</sup>	-6.3 $\pm$ 18.8, p = 0.00 <sup>*</sup>	1	-2.6 $\pm$ 12.8, p = 0.01 <sup>*</sup>	-1.8 $\pm$ 12.2, p = 0.07	0.6	-7.2 $\pm$ 10.5, p = 0.00 <sup>*</sup>	-7.8 $\pm$ 11.8, p = 0.00 <sup>*</sup>	0.6	-15.1 $\pm$ 18.0, p = 0.00 <sup>*</sup>	16.2 $\pm$ 21.5, p = 0.00 <sup>*</sup>	0.8

outcomes, the intervention and control groups showed similar decreases in negative attitude towards diabetes and similar increases in the number of subjects that received insulin and anti-hypertension treatment, in Kin-réseau and FiLDCare.

The baseline characteristics of the participants in the MoPoTsyo programme, such as HbA1C and BMI, were more favourable than those of participants in the other programmes. Nevertheless, participants in the MoPoTsyo programme displayed many indicators that worsened over the study period. Coincident with the reduction in the frequency of contact with the educator, we observed reduced percentages of subjects that performed glucose self-monitoring. These changes might be explained by the scaling up that occurred in the routine MoPoTsyo programme, within the national strategy; this process led to uncertainty among staff and patients and delays in payments [29].

### Limitations

The limitations of our study included the design and rate of the LTFU variable, the heterogeneity of the implementation of the intervention and the tools used for data collection, and the lack of intention-to-treat (ITT) analysis.

The LTFU rate was different in each programme. Some of the subjects that were LTFU had died or became seriously ill, which implied that these subjects had worse health outcomes than those that completed the study. However, the LTFU rates were comparable between the intervention and control groups; therefore, the LTFU rates were unlikely to have influenced the estimated intervention effects. Nevertheless, the particularly high LTFU rate in FiLDCare, which reflected the discontinuation of the study at the largest site, made it difficult to interpret findings from that programme. Nevertheless, the LTFU rates for the two remaining FiLDCare study sites were comparable to the LTFU rates in the other two programmes, both in number and in causes. These differences in LTFU rates justified the separate analyses for each programme. This limitation was foreseen, and it was accounted for in the original sample size calculation. An ITT analysis would have further reduced the differences between intervention and control groups.

Although we anticipated a risk of contamination between the intervention and control groups, through contacts between patients of different groups, the fact that contamination occurred was another study limitation [14]. Programme managers and educators reported that patients of different groups exchanged messages. In addition, some contamination probably stemmed from educators that were aware of the contents of DSMS text messages, and incorporated similar content into their routine DSME protocol; thus, the DSMS content reached both groups. In Kinshasa, patients visited the educator to ask additional questions; this activity contributed to greater interactions. However, this contamination can also be regarded as a (welcome) strengthening of the routine programme.

The implementation of the intervention was more problematic than foreseen. Technological barriers limited the abilities to target messages to specific individuals, to tailor text messages to the (different) patient's needs, and to reach all the participants. Moreover, the commercialisation of the SMS market resulted in subjects becoming overwhelmed with messages, which led to a degree of lethargy in reading them. The organisational capacity required to develop and send messages regularly varied across programmes. This variation led to differences in message frequency and coverage efficacy across the three programmes [16]. The coverage was best in Kin-réseau, where more than half of the patients remembered receiving most messages. Better coverage appeared to be linked to better results.

Although we used a theoretical framework in designing the intervention, it was difficult to target behavioural beliefs in the

message texts. For data collection, we implemented a scale from the Diabetes Care Profile, which measured overarching concepts, such as the feeling of control and the attitude towards diabetes, instead of specific behavioural beliefs. Most of these scales produced homogeneous scores between groups. Thus, these instruments had limited value for detecting differences between contexts or over time.

### *This study from a larger perspective*

Two meta-analyses have reported that mobile phone interventions and automated text messages have had mixed effects on glycaemic control in patients with type 2 diabetes [11,13]. A number of studies in developing countries demonstrated that SMS messaging had a positive impact on HbA1C [30,31]. However, most previous studies only lasted 6 months to a maximum of 1 year; in contrast, our study lasted 2 years. Moreover, our study included a wide variety of patients (e.g., different diabetes durations, different antidiabetic therapies), in contrast to many other studies, which selected more homogeneous cohorts, for instance, only patients on oral treatment [30]. Some previous studies combined SMS with other tools [32], and only few studies reported on intermediate outcomes. Thus, it has been difficult to unravel the mechanisms of change [13].

The SMS messaging in our study had been conceptualised as behavioural support, based on other studies that had provided some evidence of success [9]. However, if the messages were not perceived as support, their potential effect would have been influenced [33]. Our theory of change stated that DSMS works through the mechanism of increasing patient knowledge and perceptions. Therefore, an absence of measurable changes in these indicators could explain the lack of effect on the final outcomes. It is also possible that other, unrevealed covariates interfered with the relationship between the intervention and HbA1c. Personal and disease-related characteristics of the patient, and characteristics of the routine care could have had stronger influences than expected for health outcomes. From a process analysis, we learned that the number of participants that used their phone on their own initiative to call or send SMS messages about issues related to diabetes increased in all three countries. Patients most frequently contacted their educator, their doctor, and other patients. In-depth analyses of the interdependency between the intervention goals, the intermediate outcome, and the final outcome might explain some elements of this study [34]. Our study was performed in three different programmes, and in each programme, participants had different baseline characteristics and health indicators. It is known that HbA1C gradually increases over time, by an average of roughly 1% (10.9 mmol/mol) over 2 years. However, it is less clear how the duration of disease, quality of care, and different phenotypes of diabetes impact this trend [35,36].

Another explanation for the absence of an effect might be that we did not measure alternative indicators. That is, potential effects of the DSMS intervention might have been realised, not through the mechanism of increased knowledge or better coping skills, but through patients receiving improved care. For example, more people may have started taking insulin or received improved education on routine care. The fact that similar studies have shown a positive effect on HbA1c without a substantial change in behaviour also suggested that other pathways might have influenced the effects [37]. These effects would most likely spill over into the control group, which would reduce our ability to detect differences.

Lessons learned from our research were related to the design and implementation, to the extent of diabetes control in programmes in LMICs, and to the expected effect of mHealth. The integration of a long-term health intervention into a diabetes care and self-management programme requires high organisational capac-

ity. There is a substantial risk of patients dropping out of the study, due to death, migration, and other patient priorities. The dropout rate is relevant, both for research and for the organisation of health care and self-management programmes for people with chronic life-long conditions, in general. Therefore, it is important to gain a better understanding of the reasons for LTFU events and to address them. The health outcomes of participants are largely determined by personal and disease-related characteristics, by the content of care, and by the programme's approach to chronic illness and self-management. A simple, static mHealth intervention, like sending SMS messages about diabetes control, appeared to have marginal potential, compared to other factors. Although mHealth can be a useful tool for health providers, in reaching out to patients, it might be more interesting to examine more dynamic mechanisms for increasing mutual connectivity between patients, providers, and support systems.

### Conclusions

This study reported results from a RCT that tested an mHealth intervention for diabetes control in three different LMICs, with a long-term follow-up of 2 years. Our study did not show a benefit of adding the mHealth intervention to existing care and self-management programmes. The absence of an effect might be explained by the variety of patients and disease-related characteristics, the inhomogeneous implementation of the intervention, and/or the influences that the routine programme might have had on the outcomes.

### Author contributions

JVO was the coordinating investigator of the study and drafted the first version of the manuscript. KC and JDM contributed to the data analyses. GMK was in charge of the study in the Philippines; MVP was in charge in Cambodia; and JCK and CD were in charge in the DR Congo. HH performed the field-work coordination in Cambodia, including the development of SMS messages. KVA contributed substantially to the interpretation of the results, and thus, to the Discussion section. DK and BM contributed to the adaptation of the intervention and to the interpretation of the results, which were important in writing this paper. FS supervised the drafting of this manuscript and commented on all phases, from setting-up the paper to the final version. GK was the principal investigator of the study from the start. He also contributed to the Methods section and the interpretation of results.

### Duality of interest and Acknowledgement

KVA was the chair of the International Working Group on the Diabetic Foot of the International Diabetes Federation. MVP was executive director of MoPoTsyo. HH was an employee of MoPoTsyo. CD was a volunteer at Memisa Brussel. JCK was employed by Memisa DR Congo. GMK was the initiator of the FiLDCare project. FS had no conflict of interest. GK was the principal investigator of the TEXT4DSM study, but he had no financial conflict of interest. JVO was the coordinating investigator of the TEXT4DSM study. JVO takes full responsibility for the contents of the article.

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### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.jcte.2016.12.005>.

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