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Long-term follow-up of a randomized controlled trial of a text-message diabetes self-management support programme, SMS4BG

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What's new?

- Innovative interventions are needed to address the growing burden of diabetes and associated long-term complications.
- Text-messaging interventions are ideal for expanding self-management support for people with diabetes given the ubiquity of mobile phones and their reach among people in their everyday lives where self-management of diabetes is crucial.
- This study provides evidence that improvements in glycaemic control resulting from an automated text-message diabetes self-management support programme are sustained at 2 years.
- Text messaging can be an effective way of providing individually tailored support to people with diabetes outside the clinic environment.

Abstract

Aims To determine the long-term effectiveness of an individually tailored text-message diabetes self-management support programme, SMS4BG, on glycaemic control at 2 years in adults with diabetes with an HbA_{1c} concentration > 64 mmol/mol (8%).

Methods We conducted a 2-year follow-up of a two-arm, parallel, randomized controlled trial across health services in New Zealand. Participants were English-speaking adults with type 1 or 2 diabetes and with an HbA_{1c} >64 mmol/mol (8%). In the main trial, participants randomized to the intervention group (N=183) received up to 9 months of an automated tailored text-message programme in addition to usual care. Participants in the control group (N=183) received usual care for 9 months. In this follow-up study, 293 (80%) of 366 randomized participants in the main trial were included. The primary outcome measure was change in glycaemic control (HbA_{1c}) from baseline to 2 years. Mixed-effect models were

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used to compare the group differences at 3, 6, 9 and 24 months, adjusted for baseline HbA_{1c} and stratification factors (health district category, diabetes type and ethnicity).

Results The decrease in HbA_{1c} at 2 years was significantly greater in the intervention group [mean (SD) –10 (18) mmol/mol or –0.9 (1.6)%] compared with the control group [mean (SD) –1 (20) mmol/mol or –0.1 (1.8)%], with an adjusted mean difference of –9 mmol/mol (95% CI –14, –5) or –0.8% (95% CI –1.2, –0.4; P<0.0001).

Conclusions Improvements in glycaemic control resulting from a text-message diabetes self-management support programme were sustained at 2 years after randomization. These findings support the implementation of SMS4BG in current practice.

(Australian New Zealand Clinical Trials Registry Study ID no.: ACTRN12614001232628 Link: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=367369; Universal Trial no.: U1111-1162-7072)

Introduction

Alleviating the growing prevalence and burden of diabetes is a priority internationally [1]. Addressing the health inequalities seen for people from ethnic minority populations, such as Māori people (New Zealand indigenous population) and Pacific Islanders, is a priority. These populations not only experience a higher prevalence of the condition but also higher rates of associated long-term complications [2–6]. People with HbA_{1c} levels > 64 mmol/mol (8%) are at higher risk of the development of complications of diabetes, which are not only debilitating for the individual but are also costly to healthcare systems [7]. Improvements in blood glucose control can delay or prevent these complications which, in turn, can lead to improvements in quality of life for the patient and a reduction in the costs resulting from the management and treatment of complications [8–12].

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Engagement with diabetes self-management is critical for good glycaemic control and there is a need for novel tools to better help people self-manage the condition. Text messages (SMS) have the advantage of universal use, and given the ubiquity of mobile phones, may be the ideal platform for delivering self-management support within day-to-day life. While the evidence supporting the use of mobile health (mHealth) in diabetes is growing [13–15], there is little reported evidence of the sustainability of these effects over longer follow-up periods.

The SMS4BG (Self-Management Support for Blood Glucose) programme was developed to provide accessible diabetes support to adults with an HbA_{1c} > 64 mmol/mol (8%). The theoretically based text-message programme provides individualized motivation and support as well as information and reminders to engage in diabetes self-management behaviours. Extensive end-user engagement and formative work was undertaken to inform the development of the programme, which has been previously described [16]. SMS4BG was found to be acceptable and perceived to be useful in a pilot study [16], and a pragmatic randomized controlled trial (RCT) found it to result in modest but significant improvements in glycaemic control at 9 months' follow-up [17].

Given the chronic nature of diabetes and the long-term complications associated with poor control of the condition, evidence of the sustainability of these effects over a longer-term is needed. The aim of the present follow-up study was to investigate the long-term effectiveness of the programme at 2 years post initial randomization.

Methods

The study protocol and results of the main SMS4BG trial have been reported previously [17,18]. In summary, a 9-month, two-arm, parallel, RCT to assess the effectiveness of the SMS4BG intervention was conducted between June 2015 and August 2017. 1 adults (≥16

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years) with type 1 or 2 diabetes. Eligible participants had to have had an $HbA_{1c} \geq 65$ mmol/mol [> 64 mmol/mol (8%)] in the preceding 9 months, were residing in New Zealand, had to be English-speaking, and were required to have access to any type of mobile phone and to be available for the duration of the 9-month study.

Eligible participants were randomized 1:1 to either the intervention or control group, stratified by health district category (high urban district or high rural/remote), type of diabetes (1 or 2), and ethnicity (Māori and Pacific Islander, or non-Māori/non-Pacific Islander). The randomization sequence was computer-generated using variable block sizes of two or four. Participants were randomized at the completion of the baseline interview using the REDCap™ randomization module which guaranteed treatment allocation was concealed until the point of randomization. Participants allocated to the intervention group received the SMS4BG programme in addition to usual care, whereas participants allocated to the control group received usual care only. Follow-up telephone interviews were carried out at 9 months post-randomization. All HbA_{1c} blood tests were undertaken as part of routine patient care with results obtained through the patient medical records.

At the time the main study was completed, funding was not available for any further follow-up. In New Zealand it is not always acceptable to participants to receive 'usual care' for their participation in a research study, therefore at completion of the main trial, the first 87 participants in the control group (the number was limited due to funding and time constraints) were offered the SMS4BG intervention. Of those offered, 64 (74%) accepted and received the intervention for up to 9 months. Subsequently we were successful in obtaining further funding for longer-term follow-up of the participants. To compare intervention and control group participants at 2 years' follow-up, we therefore had to exclude the control participants who had subsequently received the intervention.

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available to view on a website or, if they had no internet access, these were emailed in hard copy form. Examples of messages can be seen in Fig. 1. The timing and frequency of messages, as well as the duration of the programme, was individually tailored, with message delivery managed by a content management system developed for this project. The programme was delivered at no cost to participants on any New Zealand mobile network.

Outcome measure

The primary outcome measure of this follow-up study was change in glycaemic control from baseline to 2 years, measured according to HbA_{1c} values.

Statistical analysis

Sample size calculations were conducted for the main trial (n=366; 183 per arm), which provided 80% power at 5% significance level to detect a clinically meaningful group difference of 5.5 mmol/mol (0.5%) in HbA_{1c} at 9 months, assuming a standard deviation of 18.6 mmol/mol (1.7%). For this follow-up study, statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All statistical tests were two-sided at a 5% significance level. Analyses were performed on the principle of intention-to-treat, including all randomized participants who provided at least one valid measure on the primary outcome post-randomization. Demographics and baseline characteristics of all participants followed up at 2 years were summarized by treatment group using descriptive statistics. A random-effects mixed model with an unstructured covariance was used to evaluate the effect of intervention on HbA_{1c} at 3, 6, 9 and 24 months, adjusting for baseline HbA_{1c} and stratification factors and accounting for repeated measures over time. Adjusted mean differences in HbA_{1c} between two groups were estimated at each visit, by including an interaction term between treatment and month. Missing data on the outcome were taken into account in modelling based on the missing-at-random assumption. Both 95% CIs and P

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values were reported. Model-adjusted estimates on the treatment difference between two groups were reported, together with 95% CIs and *P* values. Because the first 87 participants to complete the main trial in the control group were offered SMS4BG, a sensitivity analysis was also carried out excluding the first 87 participants of both groups.

Results

Of the 366 randomized participants who consented to take part in the main trial (*n* = 183 per arm), 354 (*n* = 177 per arm) were included in the primary analysis at 9 months and 293 (intervention, *n* = 177 and control, *n* = 116) were eligible for follow-up at 2 years. Of those not eligible, six had died, three had withdrawn and 64 control group participants were excluded due to receiving the SMS4BG intervention at the end of the main trial (Figure 2). The final 2-year follow-up data collection was completed in March 2019 with 2-year follow-up data available for 206 participants (intervention, *n* = 127 and control, *n* = 79). The loss to follow-up rate (no 2-year follow-up data available or inability to follow up) was 28% in the intervention group and 32% in the control group. Table 1 presents the baseline characteristics for the study participants included in the 2-year follow-up. No imbalances were present with the exception of location, with a greater proportion of control participants from rural areas.

The baseline characteristics of the 64 control participants excluded from this study (those who chose to receive the intervention) did not differ from the remaining control participants with regard to any of the baseline characteristics except for location, with a higher proportion of control participants excluded living in an urban area (*P* = 0.006).

A statistically significant greater decrease in HbA_{1c} from baseline to 2-year follow-up was observed in the intervention group compared with the control group: mean (SD) −10 (18)

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mmol/mol [–0.9 (1.6)%] vs –1 (20) mmol/mol [–0.1 (1.8)%], adjusted mean difference –9 mmol/mol [(95% CI –14, –5); –0.8% (95% CI –1.2, –0.4); P<0.0001 (Table 2)].

Both diabetes type (type 1 vs 2) and ethnicity (non-Māori/non-Pacific Islander vs Māori/Pacific Islander) were statistically significant confounders in the regression model, with participants with type 2 diabetes [adjusted mean difference –4 mmol/mol (95% CI –7, –1) or 0.4% (95% CI –0.6, –0.1); P=0.01] and those in the non-Māori/non-Pacific Islander ethnic group [adjusted mean difference –5 mmol/mol (95% CI –8, –2) or 0.5% (95% CI –0.7, –0.2); P=0.002] having a greater reduction in HbA_{1c} at 2 years compared to their counterparts. Consistent with the main trial findings, there was no significant interaction between the treatment group and the subgroups (P=0.92 and P=0.63, respectively).

When the first 87 participants of both groups were excluded from the analysis, which left 96 randomized participants per group, the 2-year follow-up data were available for a total of 131 participants (intervention, n = 60 and control, n = 71). The change in HbA_{1c} from baseline to 2-year follow-up remained statistically significantly lower in the intervention group compared with the control group [mean (SD) –12 (18) mmol/mol or –1.1 (1.6) % vs 2 (18) mmol/mol or 0.2 (1.7)%, adjusted mean group difference –12 mmol/mol (95% CI –17, –6) or –1.1% (95% CI –1.6, –0.6); P<0.0001].

A decrease in HbA_{1c} from baseline to 2-year follow-up was seen in 76% of participants from the intervention group compared with 46% of participants from the control group (chi-squared test, P<0.0001). At 2 years, the HbA_{1c} levels in 28% of participants in the intervention group and 14% in the control group dropped below 65 mmol/mol (P=0.02), the level considered to indicate 'poor control' in New Zealand.

Discussion

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This paper describes the long-term follow-up of our previously reported main RCT, which demonstrated a modest improvement in post-programme (9 months) levels of HbA_{1c} in the SMS4BG intervention group compared with the control group. The long-term follow-up found that the SMS4BG programme led not only to significant improvements in glycaemic control at 2 years but to a larger effect size than was seen at 9 months. This shows that the effects seen post-programme at 9 months were sustained over 2 years, whereas the improvements in HbA_{1c} initially seen in the control group at 9 months had disappeared at 2 years.

The results of the present study, namely, a mean decrease in HbA_{1c} of 10 mmol/mol (0.9%) in those who had received the SMS4BG programme and a statistically significant group difference of 9 mmol/mol (0.8%), are clinically relevant in relation to the reduction of diabetes-related mortality and complications. Reductions in HbA_{1c} are associated with a reduced risk of diabetes complications [19], with a decrease of 11 mmol/mol (1%) in HbA_{1c} reported to be associated with a 21% reduction in deaths related to diabetes and a 37% reduction in microvascular complications (e.g. retinopathy) [19]. These significant long-term results, coupled with a high level of acceptability of SMS4BG reported by the majority of participants (reported in the main trial paper) support the implementation of SMS4BG to supplement clinical practice.

There are few other long-term follow-up studies of RCTs of diabetes self-management support programmes [20] and, in particular, none in SMS interventions [14,21,22], attesting to the significance of these findings. Although there is some evidence supporting clinically significant changes in HbA_{1c} at long-term follow-up of in-person diabetes self-management programmes [23,24], our results showing positive findings from this type of programme using a delivery method with fewer access barriers than in-person programmes is important.

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This follow-up study is based on a high-quality RCT with an objectively measured primary outcome that is commonly used in diabetes trials, allowing comparison with other programmes. It also has a pragmatic community-based study design that measures the potential impact of the intervention in the way it would be delivered if it were implemented on a large scale, that is, with little contact with researchers and alongside usual diabetes care.

We particularly focused on those who had higher HbA_{1c} results, a group with high need for support and assistance, and where a change in long-term control could have the greatest impact. The trial sample included a high proportion of participants on insulin and more than one-third were from rural areas. The sample also had a reasonably high proportion of indigenous Māori and other minority ethnicity groups who are at highest risk of diabetes and adverse outcomes from the complications of diabetes.

The intervention itself is based on theoretical constructs and techniques that have been shown to be helpful in behaviour change. It builds on our previous successful developments in mHealth for behaviour change, as well as effective diabetes self-management education principles. Importantly, it had high end-user engagement throughout the development process; it was developed with people who have diabetes and clinicians working with these people, as well as a Māori advisory group. Feedback from these people was used in the iterative development, from conceptualization, pre-testing, pilot testing and through to the final programme that was delivered in the trial. SMS4BG messages are automatically individually tailored to the needs and preferences of each individual, providing not only appropriate support but personalized intervention without additional resources. As diabetes is a condition requiring constant ongoing management, using a technology that reaches people in their everyday lives could have added benefit over traditional in-person programmes delivered away from a person's usual environment.

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The main limitation of this follow-up study is the exclusion of those in the control group who subsequently received the programme at the end of the main trial. While this was considered a 'good thing' to offer the control group participants and was appreciated by those participants, it later interfered with our ability to include all randomized participants in the 2-year follow-up analysis. As we described above, at the time we offered this to the control group we had no funding to undertake any longer-term follow-up. In comparing those control group participants who received the intervention with those who not, the only significant difference was a greater proportion of excluded control participants being from urban areas which could indicate a potential source of bias in these results. Although a significant limitation, when sensitivity analyses were performed, the treatment effect seen was even stronger.

Another limitation of the study was the loss to follow-up rate of 30% (no 2-year follow-up data available or inability to follow up). Because of the pragmatic nature of this study we relied on routinely collected data. Although people with diabetes are recommended to undergo 3-monthly HbA_{1c} testing it is clear that this was not happening for many participants. Additionally, owing to a lack of results in the time lag for follow-up, it seems likely that some patients may have moved outside the area or even outside New Zealand, meaning that sourcing results was not possible.

The limitations of the main trial and potential limitations of our intervention have been described in detail elsewhere [17].

The SMS4BG intervention provides a solution for extending diabetes self-management support that is both low-cost and easily scalable. With this study establishing the longer-term benefit, the case for offering people with diabetes the option of such simple ongoing support is more compelling. Text messaging is simple, cheap and very acceptable to our population in

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need. Text messaging is also very accessible, anyone with a mobile phone is able to receive text messages regardless of phone, plan or credit, making it ideal for reaching into population groups for whom there are no other reliable communication methods.

Since the time of the study, the authors have been working on options for implementation. Programmes such as SMS4BG are imminently scalable and are most cost-effectively implemented at a national or large scale. In order to be sustainable, methods for referral and registration need to be simple and user-friendly. Depending on the health system context, this could be through general promotion and self-registration by people who want the programme, or it could be through direct referral from healthcare practitioners if the programme can be integrated into electronic health information systems. The next steps in research should be to investigate whether large-scale implementation of such programmes can have an impact on reducing health inequalities for priority populations.

In conclusion, this study shows that improvements in glycaemic control resulting from an automated text-message diabetes self-management support programme are sustained at 2 years. These results provide support for implementation of the programme to supplement current practice.

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Competing interests

None declared.

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FIGURE 1 Example SMS4BG messages

FIGURE 2 Trial registration flowchart

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Table 1 Baseline participant characteristics

Characteristic	**Intervention group, *N*=177**	**Control group, *N*=116**
Men, *n* (%)	89 (50)	68 (59)
Ethnicity, *n* (%)		
Māori	35 (20)	29 (25)
Pacific Islander	29 (16)	8 (7)
Asian	8 (5)	7 (6)
New Zealand European	89 (50)	57 (49)
Other	16 (9)	15 (13)
Ethnicity category, *n* (%)		
Māori/Pacific Islander	64 (36)	37 (32)
non-Māori/non-Pacific Islander	113 (64)	79 (68)
Diabetes type, *n* (%)		
Type 1	63 (36)	39 (34)
Type 2	114 (64)	77 (66)
Location, *n* (%)		
High urban	120 (68)	67 (58)
High rural/remote	57 (32)	49 (42)
Smoking status, *n* (%)		
Smoker	28 (16)	26 (22)
Non-smoker	149 (84)	90 (78)
Insulin treatment, *n* (%)	138 (78)	90 (78)
Referral source, *n* (%)		
Primary care	71 (40)	47 (41)
Secondary care	101 (57)	68 (59)
Self-referred	5 (3)	1 (1)
Age group, *n* (%)		
16–24 years	25 (14)	8 (7)

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25–49 years	65 (37)	42 (36)
50–64 years	68 (38)	51 (44)
≥65 years	19 (11)	15 (13)
Mean (SD) age, years	47 (15)	49 (15)
Mean (SD) time since diagnosis, years	13 (11)	13 (10)

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Table 2 Treatment effect on HbA_{1c} values

	Intervention (*n*=177)	**Control** (*n*=116)	**Un-adjusted Mean difference (95% CI)***	***P* value for difference**	**Adjusted mean difference (95% CI)***	***P* value for difference**
HbA_{1c}, mmol/mol	Mean (SD)	Mean (SD)				
Baseline	86 (18)	83 (15)				
9 months	77 (18)	79 (17)				
2 years	76 (19)	83 (18)				
Change from baseline at 9 months	–9 (15)	–4 (17)	–5 (–8, –2)	0.004	–4 (–7, –1)	0.013
Change from baseline at 2 years	–10 (18)	–1 (20)	–10 (–15, –5)	<0.0001	–9 (–14, –5)	<.0001
HbA_{1c}, %						
Baseline	10.1 (1.6)	9.8 (1.4)				
9 months	9.2 (1.7)	9.4 (1.6)				
2 years	9.1 (1.7)	9.7 (1.7)				
Change from baseline at 9 months	–0.8 (1.4)	–0.4 (1.6)	–0.5 (–0.8, –0.2)	0.004	–0.4 (–0.7, –0.1)	0.013
Change from baseline at 2	–0.9 (1.6)	–0.1 (1.8)	–0.9 (–1.4, –0.5)	<.0001	–0.8 (–1.2, –0.4)	<.0001

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years						

*Random-effects mixed model without and with adjustment for baseline HbA_{1c}, diabetes type, ethnicity and region. Both treatment group and visit were included in the model with their interaction term. A random subject effect was added to account for repeated measures on same participant

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Example core module message:

"SMS4BG: Hi [firstname]. Welcome to the SMS4BG programme. We will be sending you text messages over the next few months to support you to manage your diabetes"

Example core module (Māori) message:

"SMS4BG: Kia ora [firstname]. Planning ahead is key to good diabetes management. Plan your meals, snacks, blood glucose testing & physical activity. Kia kaha"

Example young adult module message:

"SMS4BG: Don't let your diabetes get in the way of your social life or study/work. Taking the time to manage your diabetes now means more time for fun & friends"

Example healthy eating module message:

"SMS4BG: [hi]. Make sure you have plenty of healthy food options (e.g. chopped vegetables, unsalted nuts, yoghurt) ready for your next meal or snack"

Example exercise module message:

"SMS4BG: [hi] [firstname]. Exercising is easier with a friend. Find a friend or family member to walk, swim or attend exercise classes with"

Example stress and mood management module message:

"SMS4BG: Self-care is key to feeling good & managing stress. Good self-care involves eating well, regular exercise, good sleep & relaxation time"

Example blood glucose monitoring reminder message:

"SMS4BG: [hi] [firstname]. It's time to check your blood glucose & let us know the result by replying to this message"

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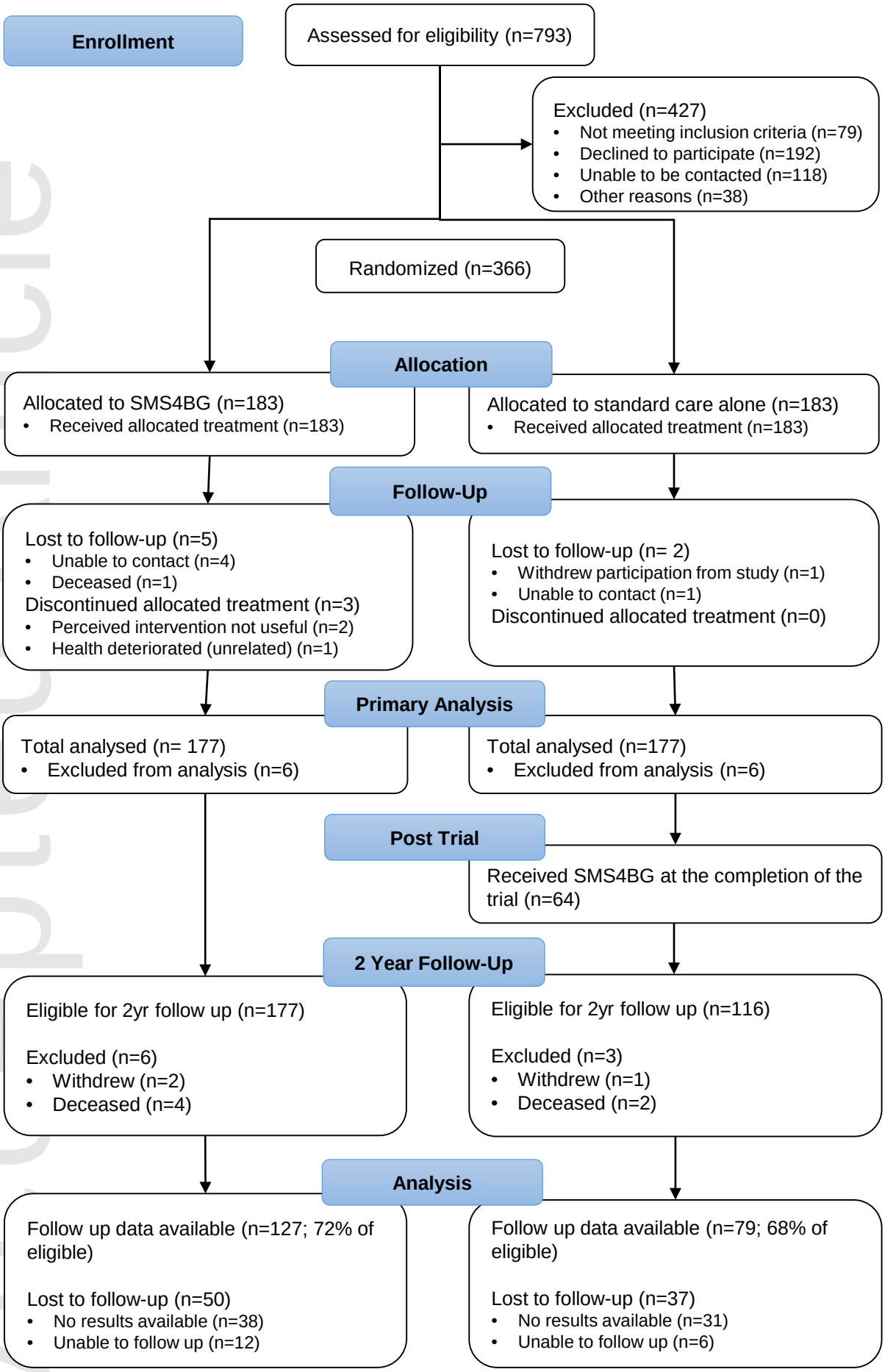

Figure 1: Trial registration flow chart

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