



Impact of the Gather mHealth System on A1C: Primary Results of a Multisite Randomized Clinical Trial Among People With Type 2 Diabetes in India

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Diabetes prevalence in India was 8.7% in 2015 and is rising because of rapid urbanization, increasing life expectancy, and a diet rich in sugar and fat (1). However, less than 20% of people living with diabetes in India achieved target A1C levels in 2011 (2). India's growing prosperity fuels this epidemic and, through increased mobile phone access, also offers pathways to improve care. A recent review of reviews confirmed the overall benefits of telemedicine in diabetes management (3), but little research has been conducted in developing countries.

A total of 91 people aged 18–65 years with type 2 diabetes, an A1C between 7.5 and 12.5% (58 and 113 mmol/mol), and an Android smartphone were recruited at three sites in Ahmedabad, Chennai, and Mumbai (March–May 2015), randomized 1:1 to the Gather mobile health (mHealth) intervention or usual care, and observed for 6 months. All received free visits, laboratory tests, and test strips and lancets. Intervention participants received the mHealth app and a mobile phone plan stipend. Data were collected through physical measurements, laboratory tests, and questionnaires.

The Gather mHealth intervention is built on behavioral change theories to support self-management, facilitate patient–provider communication, and enable treatment changes between visits using patient mobile phone apps and provider web portals and mobile phone apps.

Demographic characteristics were balanced between study arms. The 90 eligible participants had a mean A1C of 9.3% (78 mmol/mol) (SD \pm 1.2), mean age of 48.4 years (SD \pm 9.2), and median diabetes duration of 10 years (interquartile range 4–15). Thirty percent were female, 25.6% had a university education or higher, and median length of smartphone ownership was 14 months (interquartile range 7–36).

At 6 months, the 80 returning participants had a mean A1C decrease of 1.5% in the intervention group and 0.8% in the usual-care group, a statistically significant difference ($P = 0.02$; 95% CI 0.10–1.37) (Fig. 1). There were no statistically significant differences when the end point was stratified by sex, age, or length of time with diabetes. An adjusted analysis (ANCOVA) using treatment and site as factors and baseline A1C as a covariate

showed a nonsignificant difference in mean A1C results between groups ($P = 0.099$). Sensitivity analyses showed minimal baseline differences between those present and missing at end point. When using all 90 participants, results for difference in A1C were significant ($P = 0.045$) using last observation carried forward and borderline ($P = 0.06$) using imputation from treatment arm means.

To our knowledge, there are no studies of smartphone-based mHealth interventions for diabetes in India, let alone one of this rigor. However, as younger and/or wealthier individuals typically use smartphones, these results may not generalize to the wider Indian population.

These findings are similar to A1C improvements observed in international studies (4). However, a previous study of text messages in India did not show improved A1C (5). The more interactive and engaging smartphone app format may have better supported behavior change.

In this study, participants assigned to the Gather mHealth system had greater A1C reductions than those assigned to usual care. This tool could be an effective way to expand access to quality

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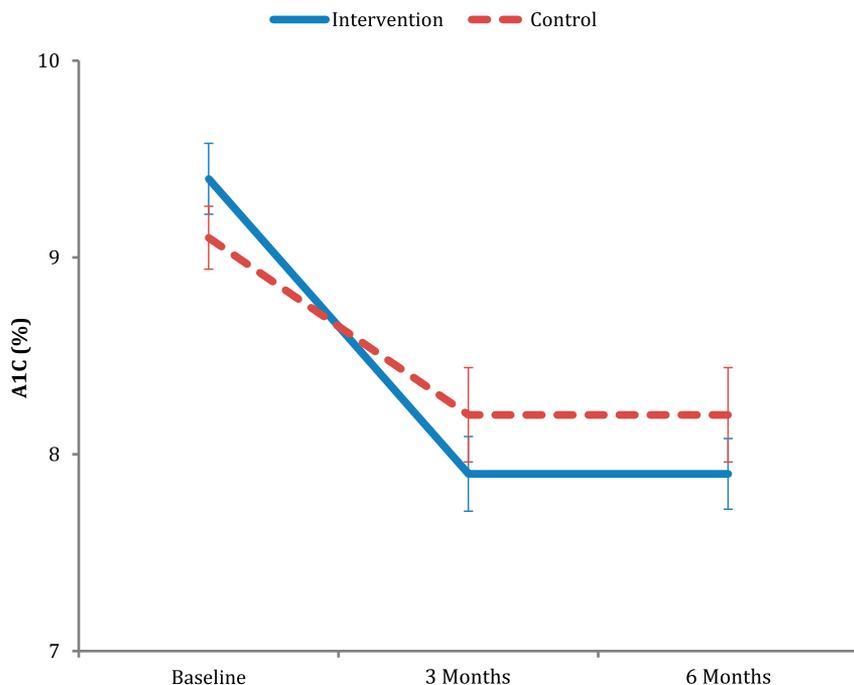


Figure 1—Mean changes in A1C from baseline to 3-month and 6-month visits.

chronic disease care and improve outcomes across India.

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