Use of Text Messages (SMS) for Assessment of Dietary Compliance Among Patients With Type 2 Diabetes Mellitus

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Committee Members: Mr. Iqbal Azam
Dr. Shariq Khoja
Dr. Jaweed Akhtar

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MSc- Epidemiology and Biostatistics (AKU)

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Introduction
Background and Objective

- According to WHO estimates 285 million individuals are suffering from Diabetes Mellitus (DM) (WHO. 2011)
- 2010 to 2030, there would be 69% and 20% increase in the number of cases of DM in developing and developed countries respectively (Shaw JE.et al.2009)
- Prevalence in Pakistan is 7.6% (IDF, Diabetes Atlas Fifth Edition.2010)

Objective:
“To assess the difference in dietary compliance in patients with type 2 DM, who were reminded through text messages (SMS) vs. those not reminded”
Rationale

• Incidence of type 2 DM is rising in developing countries
• Compliance to healthy diet is central for DM management
• Need innovative techniques for better management of type 2 DM
• Use of electronic communication is very common in Pakistan
• Text messages could be used to remind patients with type 2 DM about healthy diet

• With the help of this study;
  – We would be able to assess the role of text messaging in improving dietary compliance in diabetic patients
  – Developing policies of continuous reminders for different chronic health conditions to improve the standard and quality of life of the individuals
Methods
Methodology

• **Study design**
  – Hospital based, single blinded RCT with Block Randomization

• **Study setting**
  – This study is being carried out in Karachi Pakistan

• **Study Site**
  – Aga Khan University and Hospital (AKUH)

• **Study sample and study period**
  – Total sample size is 248 and the overall follow up period for each participant is 3 months
## Eligibility criteria

### Inclusion

- Diagnosed with known type 2 DM since 2 to 15 years
- Patients with age between 30 to 70 years
- HbA1c more than 7%
- On oral hypoglycemic medication only
- Who have mobile phone and did not intend to change their phone number in the next six months
- Could read and respond to the SMS written in Urdu

### Exclusion

- Enrolled in any other study
- Complicated diabetic cases and co-morbidities e.g. renal failure and liver cirrhosis
- Did not give informed consent.
- Not able to understand Urdu language
- Pregnant women
- Hearing and verbal disabilities
Tools used for data collection

Questionnaires
• Socio- demographic questionnaire
• Social support Questionnaire (Sallis JF. et al in 1987)
• Hospital anxiety and depression scale (HADS) (Zigmond AS. 1983)
• Food frequency questionnaire (FFQ) (Iqbal R. et al)
• Fortnightly two-item questionnaire (FTIQ)

Physical measurement
• Weight
• Height
• Hip circumference
• Waist circumference
Intervention

Text messages

Text message reminders were sent to the participant three times a week.

Frontline-SMS Software was used to send the messages by connecting with EDGE USB.
All the participants with type 2 Diabetes Mellitus coming to AKUH, Karachi $n = 2250$

Recruited sample of eligible participants $n = 115$

Complete interim analysis $n = 60$

Not enrolled (2135)

Not Meeting Inclusion Criteria ($n=1630$)

Refusals ($n=505$)

Baseline assessment
Dietary guidelines with detailed counseling

Block Randomization

Intervention Group ($n = 30$)
Text message reminder
Fortnightly two-item questionnaire

Control Group ($n = 30$)
Fortnightly two-item questionnaire

Assessment of outcome (dietary compliance score) $n=30$

Assessment of outcome (dietary compliance score) $n=30$
Results & Discussion
Results

Mean dietary compliance score using FFQ (95% CI) by Follow-up time and Intervention Status (Group)

<table>
<thead>
<tr>
<th>F-statistics (p-value)</th>
<th>Within Group</th>
<th>Between Group</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (&gt;0.99)</td>
<td>0.065 (0.79)</td>
<td>3.7 (0.059)</td>
<td></td>
</tr>
</tbody>
</table>

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Conclusions & Recommendations
Conclusion

• Findings of the interim analysis suggest that there is no effect of text messages on dietary compliance of diabetic patients

• The reasons might be reduced follow up time as compared to per protocol and low post-hoc power of interim analysis

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Recommendations for future studies

• Study should be multicenter - both public and private hospitals
• Should use patients waiting time for maximizing recruitment
• In an ideal case one should make a call after complete follow-up to know about the actual compliance rate to the intervention (reading text messages)
  or
• There should be more advance technology that could help in the confirmation of patient's reading of text messages
• The preferable technique is to use bio markers for assessing dietary compliance
• Need to understand the ideal number of messages per week for behavioral change in Pakistani population- which is unknown
THANK YOU
Presentation Outline

- Introduction
  - Background
  - Rationale
  - Research Question & Hypothesis
  - Aim & Objectives
- Methods
  - Complete procedure
  - Ethical approval and Trial registration
- Results & Discussion
  - Results
  - Discussion
- Conclusion & Recommendations
  - Conclusion
  - Recommendations

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According to WHO estimates 285 million individuals are suffering from Diabetes Mellitus (DM) (WHO. 2011)

2010 to 2030, there would be 69% and 20% increase in the number of cases of DM in developing and developed countries respectively (Shaw JE.et al.2009)

According to International Diabetes Federation (IDF), National Prevalence in Pakistan is 7.6% (IDF, Diabetes Atlas Fifth Edition.2010)
Dietary Compliance in Diabetes Mellitus

- Dietary compliance is a state of being in accordance with established dietary guidelines.
- Dietary counseling for diabetes mellitus management is helpful in improving compliance to diet (Siddiqui A. et al. 2010).

Mobile-Health

- Mobile health (M-health) is a wireless health technology.
- A review study: on behavioral change interventions delivered by mobile phone (SMS).
  - Positive outcome was observed in 13 out of the 14 studies. (UK, USA, New Zealand, Finland, Croatia and Korea) (Fjeldsoe BS. et al. 2009).
- It has been suggested that M-health can be used as an innovative approach to fight chronic diseases in South Asia (Ajay VS and Prabharkaran D. et al. 2011).
Rationale

- Incidence of type 2 DM is rising in developing countries
- Compliance to healthy diet is central for DM management
- Need innovative techniques for better management of type 2 DM
- Use of electronic communication is very common in Pakistan
- Text messages could be used to remind patients with type 2 DM about healthy diet

With the help of this study;
- We would be able to assess the role of text messaging in improving dietary compliance in diabetic patients
- Developing policies of continuous reminders for different chronic health conditions to improve the standard and quality of life of the individuals

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Research question & Hypothesis

Research Question

Is there any difference in compliance to dietary guidelines among patients with type 2 DM who receive text message reminders, compared to those who do not receive text message reminders?

Hypothesis

Compliance to dietary guidelines among patients with type 2 DM, who receive text message reminders, would be different by dietary compliance score of 1.5 as compared to patients who do not receive text message reminders.

Aim and objectives

Aim
To assess whether text messages related to dietary management of type 2 DM can improve the health of patients with type 2 DM in Pakistan

Primary objective
To assess the difference in dietary compliance in patients with type 2 DM, who were reminded through text messages (SMS) vs. those not reminded by text messages

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Secondary objectives

1. To assess dietary compliance by using responses to fortnightly two-item questionnaire for the intake of fruits and vegetables in the last 24 hours

2. To assess the difference in dietary compliance among participants who will respond to fortnightly two-item questionnaire vs. those who will not respond to fortnightly two-item questionnaire

3. To assess the change in HbA1c level of participants after 3 months of follow-up

4. To assess the change in Fasting blood glucose level of participants after 3 months of follow-up
**Methods**

- **Study design**
  - Hospital based, single blinded RCT with Block Randomization

- **Study setting**
  - This study is being carried out in Karachi Pakistan

- **Study Site**
  - Aga Khan University and Hospital (AKUH)

- **Study period**
  - The overall follow up period for each participant is 3 months
Sample size

Assumptions for sample size calculation

- Expected mean difference in compliance score of 1.5 between the two groups
- 5% level of significance
- 80% power
- 10% loss to follow-up
- 248 participants i.e. 124 in each group

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## Eligibility criteria

### Inclusion
- Diagnosed with known type 2 DM since 2 to 15 years
- Patients with age between 30 to 70 years
- HbA1c more than 7%
- On oral hypoglycemic medication only
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- Enrolled in any other study
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Tools used for data collection

Questionnaires
- Socio- demographic questionnaire
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- Hospital anxiety and depression scale (HADS) (Zigmond AS. 1983)
- Food frequency questionnaire (FFQ) (Iqbal R. et al)
- Fortnightly two-item questionnaire (FTIQ)

Physical measurement
- Weight
- Height
- Hip circumference
- Wait circumference
Intervention

Text messages

Text message reminders were sent to the participant three times a week.

Frontline-SMS Software was used to send the messages by connecting with EDGE USB.
Mean dietary compliance score

Food Consumption (FFQ) was compared to Dietary guidelines

<table>
<thead>
<tr>
<th>Consumption</th>
<th>Scoring (0-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equal consumption</td>
<td>2</td>
</tr>
<tr>
<td>Less consumption</td>
<td>1</td>
</tr>
<tr>
<td>High consumption</td>
<td>1</td>
</tr>
<tr>
<td>No consumption</td>
<td>0</td>
</tr>
</tbody>
</table>

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Outcome assessment

Compliance to diet was assessed in 2 ways

Primary objective

Food frequency questionnaire (8 food groups)

Secondary objectives

Fortnightly two-item (fruits and vegetables) questionnaire

Comparison of dietary compliance (FFQ) based on response to FTIQ

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Interim work

- In the protocol it was stated that FFQ would be administered at the baseline and after follow-up of 3 months, but because of time line issues, FFQ was decided to be administered after 1.5 months for interim analysis.

- The results of only those participants are mentioned whose follow-up of 1.5 months has been completed till mid July 2012.

- The overall recruitment, interim work and complete follow-up is still on going.
All the participants with type 2 Diabetes Mellitus coming to AKUH, Karachi n = 2250

Recruited sample of eligible participants n = 115

Complete interim analysis sis n = 60

Not enrolled (2135)
Not Meeting Inclusion Criteria (n=1630)
Refusals (n=505)

Baseline assessment
Dietary guidelines with detailed counseling

Block Randomization

Intervention Group (n = 30)
Text message reminder
Fortnightly two-item questionnaire

Assessment of outcome (dietary compliance score) n=30

Control Group (n = 30)
Fortnightly two-item questionnaire

Assessment of outcome (dietary compliance score) n=30
Statistical analysis

• Baseline characteristics
  – Histograms and Kolmogorov test for normality
  – Means and standard deviations (Age, body mass index, waist hip ratio and social support score)
  – Median and inter quartile range (household income, number of family members, number of earning members, number of physician visit, duration of diabetes, fasting blood glucose and HbA1c)
  – Frequencies (Gender, Education, current working status and anxiety and depression)

• Bivariate
  – Independent samples t-test (normally distributed variables)
  – Mann Whitney U test (skewed variables)
  – Chi square test of independence and Fisher Exact test (independent categorical variables)
Statistical analysis (continued)

• Outcome of the study
  – **Repeated Measures ANOVA** (To compared mean dietary compliance score assessed by FFQ within (pre and post) as well as between intervention and control arms)
  – **Mann Whitney U test** (To compared mean dietary compliance score assessed by fortnightly two-item (fruits and vegetables) questionnaire between the study arms)
  – **Two Way ANOVA** (Difference in mean dietary compliance score (FFQ) among those who responded to fortnightly two-item questionnaire vs. those who did not respond by intervention status)

• Post hoc power Analysis
  – Post hoc power was calculated for all the variables

• Software used for the Analysis
  – We used **SPSS-19** for the analysis of the data and **PASS 2008** for the assessment of the power of the study for the sample size achieved
Results & Discussion
Baseline characteristics of the study participants

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Median &amp; IQR Intervention (n=30)</th>
<th>Median &amp; IQR Control (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.77 (9.94) *</td>
<td>51.33 (9.79) *</td>
</tr>
<tr>
<td>Gender (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22</td>
<td>15</td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Social support score</td>
<td>48.23 (4.30) *</td>
<td>49.77 (6.63) *</td>
</tr>
<tr>
<td>Education (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ Matriculation</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>≥ Intermediate</td>
<td>22</td>
<td>16</td>
</tr>
<tr>
<td>Household income (RS)</td>
<td>50000 (40000, 100000)</td>
<td>50000 (28750, 100,000)</td>
</tr>
<tr>
<td>Fasting blood sugar (mg/dl)</td>
<td>145 (128.8, 175.5)</td>
<td>132.5 (113.8, 148)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8 (8, 9)</td>
<td>8 (7, 9)</td>
</tr>
<tr>
<td>Anxiety and Depression (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Anxious</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Depressed</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Anxious and Depressed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Mean (Standard Deviation)
Mean dietary compliance score using FFQ (95% CI) by Follow-up time and Intervention Status (Group)

<table>
<thead>
<tr>
<th></th>
<th>Within Group</th>
<th>Between Group</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>p-value</td>
<td>0 (&gt;0.99)</td>
<td>0.065 (0.79)</td>
<td>3.7 (0.059)</td>
</tr>
</tbody>
</table>

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# Mean dietary compliance score using FTIQ by Intervention Status (Group)

<table>
<thead>
<tr>
<th>Compliance score</th>
<th>Intervention Mean (SD)</th>
<th>Control Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.33 (1.12)</td>
<td>0.967 (1.13)</td>
<td>0.22</td>
</tr>
</tbody>
</table>
Comparison of dietary compliance (FFQ) by response to fortnight by two-item questionnaire

![Graph showing comparison of dietary compliance by response to fortnight by two-item questionnaire.](image)

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>Degree of freedom</th>
<th>Mean Square</th>
<th>F Statistics</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>.429</td>
<td>3</td>
<td>.143</td>
<td>.447</td>
<td>.721</td>
</tr>
<tr>
<td>Intervention Status</td>
<td>.067</td>
<td>1</td>
<td>.067</td>
<td>.209</td>
<td>.650</td>
</tr>
<tr>
<td>Response Status</td>
<td>.351</td>
<td>1</td>
<td>.351</td>
<td>1.097</td>
<td>.299</td>
</tr>
<tr>
<td>Intervention Status* Response Status</td>
<td>.011</td>
<td>1</td>
<td>.011</td>
<td>.035</td>
<td>.852</td>
</tr>
<tr>
<td>Error</td>
<td>17.905</td>
<td>56</td>
<td>.320</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>18.333</td>
<td>59</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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## Discussion

<table>
<thead>
<tr>
<th>Author and year of the study</th>
<th>Study setting</th>
<th>Nature of intervention Sample size and follow-up</th>
<th>Outcome of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ina Kristina.Pangan.et al. 2011</td>
<td>Philippines</td>
<td>Text messages (n= 24) Follow-up = 21 days</td>
<td>No sig difference in dietary compliance</td>
</tr>
<tr>
<td>Shetty AS.et al. 2011</td>
<td>India</td>
<td>Text messages (n= 200) Follow-up = 12 months</td>
<td>No sig improvement in the dietary compliance</td>
</tr>
<tr>
<td>Franklin VL.et al. 2006</td>
<td>USA</td>
<td>Text messages (n= 92) Follow-up = 12 months</td>
<td>Significant improvement in Diabetes self-efficacy and compliance to medications</td>
</tr>
</tbody>
</table>

*Nutrition Research Symposium:2013*
<table>
<thead>
<tr>
<th>Variables</th>
<th>Calculated Power (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary compliance score (FFQ)</td>
<td>24</td>
</tr>
<tr>
<td>Dietary compliance score (Fortnightly two-item questionnaire)</td>
<td>23</td>
</tr>
<tr>
<td>Age in years</td>
<td>8</td>
</tr>
<tr>
<td>Gender</td>
<td>46</td>
</tr>
<tr>
<td>Education</td>
<td>37</td>
</tr>
<tr>
<td>Current working status</td>
<td>26</td>
</tr>
<tr>
<td>Social support score</td>
<td>24</td>
</tr>
<tr>
<td>Household income (RS)</td>
<td>8.6</td>
</tr>
<tr>
<td>Family members in numbers</td>
<td>5</td>
</tr>
<tr>
<td>Earning members in numbers</td>
<td>1</td>
</tr>
<tr>
<td>Body mass index in kg/m²</td>
<td>43</td>
</tr>
<tr>
<td>Waist hip ratio in cm</td>
<td>59</td>
</tr>
<tr>
<td>Number of physician visits</td>
<td>25</td>
</tr>
<tr>
<td>Duration of Diabetes (Years)</td>
<td>6</td>
</tr>
<tr>
<td>Anxiety and Depression</td>
<td>9.6</td>
</tr>
<tr>
<td>Fasting blood sugar (mg/dl)</td>
<td>57</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>3.7</td>
</tr>
</tbody>
</table>
Reasons for not achieving sample size

- Initially **three study sites** were decided for recruitment of the study participants – finally **one site (AKUH)** was selected

- Patients flow to the study site (AKUH) was less than estimated
- Some eligible **patients were enrolled** in other dietary intervention studies going on simultaneously
- Unable to recruit participants from inpatients wards
- Unable to use the **patient's waiting time** for recruitment and baseline interview because of restrictions from the department
- Eligible diabetic patients on **initial visit** in the clinic were not recruited because dietary counseling was provided to them as per AKUH policy

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## Strengths and Limitations

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized control trial</td>
<td>Small sample size: low power of the interim analysis</td>
</tr>
<tr>
<td>Blinding: outcome assessors</td>
<td>Short duration of the follow-up: (1.5 months) may be insufficient for behavioral change intervention (Morin CM. et al. 1999)</td>
</tr>
<tr>
<td>Block randomization</td>
<td>FFQ was administered through telephone calls for the assessment of outcome</td>
</tr>
<tr>
<td>Urdu text messages: designed for Pakistani population.</td>
<td>Recall bias and response bias in the assessment of the outcome</td>
</tr>
<tr>
<td>Validated tools</td>
<td>Patients might not read the text messages in the intervention arm</td>
</tr>
<tr>
<td>Credit transfer for responding to text messages</td>
<td>Unable to assess the change in HbA1c as well as fasting blood glucose due to short follow up period</td>
</tr>
</tbody>
</table>
Conclusions & Recommendations
Conclusion

• We are unable to make conclusion about the relationship of dietary text message reminders and dietary compliance in type 2 diabetic patients

• Findings of the interim analysis suggest that there is no effect of text messages on dietary compliance of diabetic patients

• The reasons might be reduced follow up time as compared to per protocol and low post-hoc power of interim analysis
Recommendations for future studies

- Study should be multicenter - both public and private hospitals
- Should use patients waiting time for maximizing recruitment
- In an ideal case one should make a call after complete follow-up to know about the actual compliance rate to the intervention (reading text messages)
  or
- There should be more advance technology that could help in the confirmation of patient's reading of text messages
- The preferable technique is to use bio markers for assessing dietary compliance
- Need to understand the ideal number of messages per week for behavioral change in Pakistani population- which is unknown
<table>
<thead>
<tr>
<th>Author, Year of Study</th>
<th>Place of study</th>
<th>Study site, Sample size</th>
<th>Prevalence (%) of Type 2 DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. S. Shera, 1995</td>
<td>Shikarpur</td>
<td>Community, 967</td>
<td>Male: 9  Female: 6.3</td>
</tr>
<tr>
<td>A.S. Shera et al, 1999</td>
<td>KPK (Pakistan)</td>
<td>Community, 1035</td>
<td>Male: 9.2  Female: 11.6  Overall: 11.1</td>
</tr>
<tr>
<td>A.S. Shera. et al, 1999</td>
<td>Baluchistan (Quetta, Killimengal)</td>
<td>Community, 1404</td>
<td>Male: 11.1  Female: 10.6  Overall: 10.8</td>
</tr>
<tr>
<td>A. Basit et al, 2002</td>
<td>Baluchistan</td>
<td>Community, 2032</td>
<td>Male: 10.1  Female: 4.3  Overall: 6.3</td>
</tr>
<tr>
<td>A.S. Shera. et al, 2007</td>
<td>All four provinces of Pakistan</td>
<td>Community, 5433</td>
<td>Male: 6  Female: 3.5</td>
</tr>
<tr>
<td>Zafar J et al 2011</td>
<td>Rawalpindi</td>
<td>Community, 31091</td>
<td>Male: 15.41  Female: 12.31  Overall: 13.14</td>
</tr>
</tbody>
</table>
Role of Telemedicine in disease management

Telemedicine is the use of medical information exchanged from one site to another via electronic communications. Key purpose of telemedicine is to improve patients' health status.

• Various forms of IT are being used for this purpose e.g. Internet, Mobile phone calls, Text messages (SMS) and TV programs etc. (Kareem S.et al.2004)

• In developing countries implementation of telemedicine is at the beginning stage as compared to developed countries. (Wootton R. 2008)

• However, high cost, poor infrastructure and absence of technical expertise are considered to be major hurdles in implementing telemedicine. (WHO. 2009)
USE OF MOBILE PHONE IN HEALTH CARE PROVISION

- St. Gabriel's Hospital Malawi. community health workers were supplied with mobile phone (2009).
  - Total 2,048 hours of working time were saved.
  - Fuel savings were $2,750.
  - Capacity of tuberculosis treatment program was doubled, up to 200 patients (28).

- A study was conducted in USA (2009).
  - Instrument contains camera-enable mobile and microscope eye piece.
  - Early diagnosis of infectious diseases in those settings where technical equipment's are not available (29).

- A randomized controlled trial conducted in Kenya (2010)
  - Those who were being reminded through mobile text messages showed a greater adherence to the antiretroviral treatment
  - RR for non-adherence was 0.81, 95% CI 0.69-0.94; p=0.006 (30).

- Another trial conducted in Korea:
  - Found a significant decrease in the HbA1c (-1.3 in intervention arm) (31).
Study design

- A hospital based, single blinded, randomized controlled trial.
- **Intervention arm**: received written dietary guidelines with counseling, a text message reminder and fortnightly SMS.
- **Control arm**: received only dietary guidelines with counseling and fortnightly SMS.
- Study participants were randomly assigned to either arm with **block randomization** (of varying length i.e. 2 and 4) technique.
- Text messaging was used as an intervention to improve the compliance to dietary guidelines.
- Text messages were sent on the mobile phones by using **Frontline Short Message Service** software three times a week for three months.
Study Population

All diabetic patients living in Pakistan

Target Population

All diabetic patients who were coming to study site

Source Population

Diabetic patients of 30 to 70 years, diagnosed as confirmed case of Type 2 DM in the last 2 to 15 years

Study Population

Study sample n=248

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Covariates

- **Age (years)**
  - As age increases a person’s ability to respond to the text messages and following the dietary guidelines both can be affected.
  - It was assessed both from patient and the medical records (which contains date of birth of the patient).

- **Education**
  - Education can alter the effect of intervention suggested by a study conducted in India.
  - Education was assessed with the help of questionnaire as a categorical variable.

- **Social support**
  - Social support is defined as the perceived availability of people whom the individual trusts and who show care for the individual.
  - Social support can confound the results, those who will have support from the family members will be more compliant as compared to those who do not have. Assessed by questionnaire.

- **BMI**
  - It was assessed by measuring weight and height (wt in kg/ ht in meters square) with weight and height scales.
  - Patients with high BMI have less control on diet as compare to those with normal BMI.
Family income
- Family income shows the ability of an individual to purchase the food items for consumption.
- Income was assessed as a continuous variable.

Number of family members
- Number of family members affects the participant’s adherence to dietary guidelines.
- Lower dietary adherence in participants was found with increasing number of family members.
- It included all those family members who are sharing same kitchen with the participants.

Number of physician’s visit
- If the physician’s visits increases, compliance to dietary guidelines can be improved.
- Participants were asked that how many times you had visited the physician regarding DM in the last three months.

Depression and anxiety
- Depression can affect the compliance of an individual.
- Depression and anxiety were measured with the help of the hospital anxiety and depression (HAD) scale.
- There were total 14 questions, 7 were about anxiety and 7 were about depression. Each question carries four options, with a fixed score (0 to 3).
Dietary intake assessment

Food frequency questionnaire (FFQ)
• A FFQ was conducted at the baseline as well as after the follow-up.
• There were 8 main food groups in the FFQ e.g.
  – Cereals group and meat group.
  – Each food group consisted of many food items.
• Frequency of intake of each food item was recorded in one of the 9 categories which ranged from
  – Never, ≤ once/month, 1-3 times/month, 1 time/week, 2-4 times/week, 5-6 times/week, 1 time/day, 2-3 times/day, 4-5 times/day and ≥ 6 times/day.

Fortnightly two-item questionnaire (FTIQ)
• A FTIQ was sent to assess compliance to dietary intake of specific food groups in both the study arms i.e. fruits and vegetables.
**Outcome variable**

- Mean dietary compliance score based on frequency of food group consumption per day.
  - Initially frequency of intake was converted into per day intake in case of FFQ.
  - Multiplied with the amount of intake.
  - Mean daily intake for each food group was calculated.
  - Assigned scores.
  - Calculated over all mean compliance score for each participant.

<table>
<thead>
<tr>
<th>Food Consumption (FFQ) was compared to Dietary guidelines</th>
<th>Scoring (0-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equal consumption</td>
<td>2</td>
</tr>
<tr>
<td>Less consumption</td>
<td>1</td>
</tr>
<tr>
<td>High consumption</td>
<td>1</td>
</tr>
<tr>
<td>No consumption</td>
<td>0</td>
</tr>
</tbody>
</table>
Pretesting

- Sample of 10 participants.

Original plan vs. Amendments

- Only women were decided earlier to recruit in the study.
- Recruited both, male and female participants in the study
- Initially incident cases were decided.
- Prevalent cases (2-15 years of diagnosis of type 2 DM) were recruited.
- Age 40 to 65 years.
- Age of 30-70 years.
- Earlier it was suggested to conduct the study at three different settings.
- Recruited participants only from AKUH.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Reference</th>
<th>Analysis</th>
</tr>
</thead>
</table>
| Social Support                   | Sallis JF. et al. 1987  | • 6 positive question  
• 7 negative questions  
• Each question was assigned scores from 1 (never) to 5 (very frequently)                                                               |
| Anxiety and Depression           | Zigmond AS, Snaith RP. 1983 | • There were total 14 questions, 7 were about anxiety and 7 were about depression.  
• Each question carries four options, with a fixed score (0 to 3).                                                                 |

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DATA MANAGEMENT AND QUALITY CONTROL

- Data collectors were trained
  - Classroom teaching
  - Practical experience.

- Data collection was done under the supervision of the Principal Investigator.
  - Review of each filled questionnaire
  - Spot checks of the data collectors

- Editing at study site (data collector).
- Editing at office (Principal Investigator).
- Double data entry was done (Cleaning)
- Logical cleaning was also done by checking for wild codes and skip patterns etc.
**Discussion**

- First m-health study in diabetic patients to assess the dietary compliance in Pakistan.

- Interim analysis found that the mean difference in dietary compliance score using FFQ was not significant both within the groups as well as between the groups.

- Marginally significant interaction between factor and group variable. That mean dietary compliance was changed in the intervention arm (decreasing) differently as compared to control arm (increasing) from baseline to follow-up.

- Mean dietary compliance assessed for response given to fortnightly two-item questionnaire was also not different between intervention and control arm.

- Mean dietary compliance score using FFQ was not different by response to fortnightly two-item questionnaire and intervention status.

Nutrition Research Symposium:2013
- In a similar study on the effect of text messages conducted in the Philippines on obese participants (n= 24, Duration: 21 days). (Ina.Kristina.Pangan.et al.2011)
  - No sig difference in dietary compliance.
  - Sig improvement in knowledge.

- A pilot study with a follow-up period of one year in India on diabetic participants (n: 215) with a secondary objective of improving dietary compliance by giving text messages was assessed. (Shetty AS.et al.2011)
  - Found no sig improvement in the dietary compliance
  - Reported that small sample size could be a reason for this association while doing subgroup analysis.

- Another study conducted in Korea to assess impact of nurse telephone calls on adherence to diabetes control recommendations. After follow-up of 12 weeks. (Kim and Oh.2003)
  - Adherence to diet was improved by a score of 10.06 in the intervention arm significantly.

Nutrition Research Symposium:2013
A study conducted on effect of telephone follow-up on adherence to a diabetes therapeutic regimen in Iran. (Nesari M.et al.2010)
- Mean compliance score was improved by 17.6 points from baseline to follow-up in the intervention arm while in the control arm 5.3 points.

A randomized controlled trial of Sweet Talk, a text messaging system to support young people with diabetes was conducted in UK. (Franklin VL.et al.2006)
- Reported SMS reminder associated with improvement in diabetes self-efficacy, self-reported adherence score was 6.8 times higher in the intervention arm (p-vale=0.042)
## Response Rate

### Response to FTIQ

<table>
<thead>
<tr>
<th>Number of Responses</th>
<th>Intervention (n)</th>
<th>Control (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responded</td>
<td>21</td>
<td>15</td>
</tr>
<tr>
<td>Not responded</td>
<td>9</td>
<td>15</td>
</tr>
</tbody>
</table>