Long-term tele-monitoring of patients with type 2 diabetes mellitus: Ancillary analysis of the results of the Greek pilot of the Renewing Health multicentre randomised control trial.

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Background and aims: Evidence is required to assess the impact of long term telemedicine use in treatment of patients with type 2 diabetes mellitus (DMT2). The aim of the present study was to examine the impact of a long-term telemonitoring program for patients with DMT2 on glycemic control, health-related quality of life (HRQOL), physical activity and compliance with the mediterranean diet compared to usual care.
Clinical Trial registration number: NCT01498367

Materials and methods: In the Greek pilot of a prospective, randomized, single-blinded, multicenter, one year study 154 patients with DMT2 capable to use the telemonitoring device, with an HbA1c > 53 mmol/mol (7.0 % according to NGSP) were studied after they were randomly assigned in the telemonitoring group (IG), (N=74) and in the control group (CG), (N=80) and having signed the informed consent form (*Image 1*). In the (IG) group patients' blood glucose profiles were collected weekly using a mobile phone platform (*Image 2*), for a period of one year. Allocated health professionals provided by phone the appropriate counseling on lifestyle and medication changes when required (*Image 3*). Patients in (CG) group received usual care with face-to-face consultations. HRQOL was assessed using a generic (SF36v2) questionnaire and a disease-specific questionnaire, the Problem Areas in Diabetes (PAID) scale. Physical activity was assessed using the self-administered short form instrument. International Physical Activity Questionnaire (IPAQ) and the compliance with the Mediterranean diet using the Mediterranean Diet Quality Index (KIDMED) adapted for Greek adults.

Results:
The table in the Image 4 presents the demographics while the table in the Image 5 shows the outcome of the variables studied in both groups. A greater reduction in HBA1C was observed in the IG compared to the CG at the end of the study. There was a statistically significant improvement in the generic HRQOL in the MCS, in the disease specific HRQOL and the physical activity in the IG compared with the CG, but there was no improvement in KIDMED in neither or the two groups.
Using linear regression analysis, no significant contribution to the reduction of HBA1C level to was proven due to patients demographics regarding age (R2 0.099, p 0,103), gender (R2 0.061, p 0,316), level of education (R2 0.034, p 0,572), prior use of computer, (R2 0.062, p 0,309), prior use of mobile phone (R2 0.005, p 0,406).
In the image 6 ancillary analysis of the outcomes is presented.

Conclusion: Our preliminary results indicate that in patients with DMT2, home telemonitoring is more effective than usual care in improving glycemic control with concurrent improvement in patients quality of life and increase of their physical activity. However home telemonitoring does not seem capable to empower patients with DMT2 with to follow a healthier diet.

Image 3

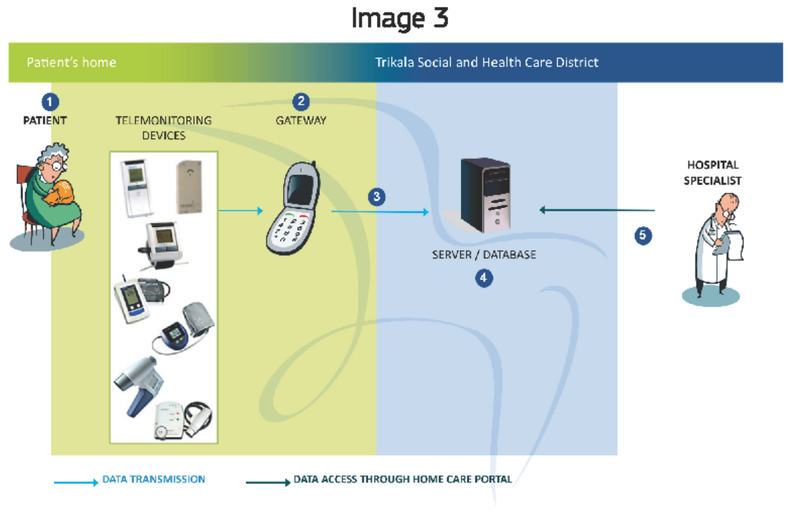

Image 1: Participants' Flow Diagram

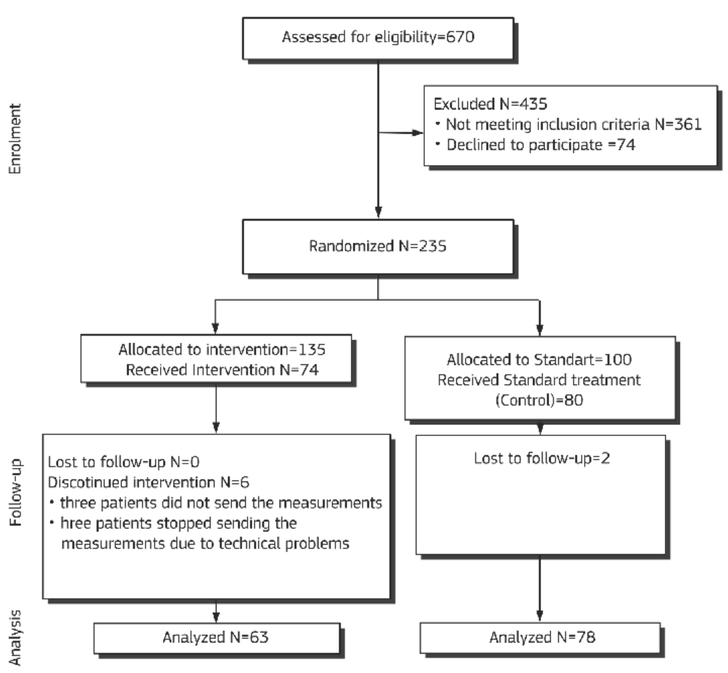

Image 2: Telemonitoring Device

Image 4: Baseline Demographics

Pilot	Central Greece	
Sample size	Intervention (N=74)	Control (N=80)
Age (years) [Mean (SD)]	58.28 (0.93)*	64.11 (0.60)*
Gender (male) [n (%)]	39 (52.70%)*	29 (36.30%)*
Height (cm) [Mean (SD)]	168.00 (1.00)*	163.15 (0.88)*
Weight (kg) [Mean (SD)]	87.20 (2.05)*	82.08 (1.76)*
Heart disease	9 (6.40%%)	12 (8.60%)
Cerebrovascular disease	0 (0.00%)	0 (0.00%)
Chronic Pulmonary disease	0 (0.00%)	0 (0.00%)
Connective tissue disease/ rheumatic disease	2 (1.40%)	2 (1.60%)
Liver disease	0 (0.00%)	0 (0.00%)
Hemiplegia	0 (0.00%)	0 (0.00%)
Renal disease	3 (2.10%)	4 (2.90%)
Cancer	1 (0.70%)	3 (2.10%)
AIDS	0 (0.00%)	0 (0.00%)
Other	25 (17.90%)	34 (24.30%)
Education		
No formal schooling	2 (2.70%)*	2 (1.30%)*
Less than primary school	0 (0.00%)*	5 (6.30%)*
Primary school	24 (32.40%)*	64 (80.00%)*
Secondary school	12 (16.20%)*	4 (5.00%)*
High school	19 (25.70%)*	3 (3.80) *
College/ University	17 (23.00%)*	3 (3.80%)*
Post graduate degree	n.a.	n.a.

Pilot	Central Greece	
Sample size	Intervention (N=74)	Control (N=80)
Marital status		
Never married	3 (3.80%)	4 (5.4%)
Currently married	70 (87.50%)	62 (83.80%)
Separated	0 (0.00%)	1 (1.40%)
Divorced	0 (0.00%)	3 (4.10%)
Widowed	7 (8.80%)	4 (5.40%)
Cohabitating	n.a.	n.a.
Work status**		
Government employee	9 (12.20%)*	0 (0.00%)*
Non-government employee	12 (16.20%)*	5 (6.30%)*
Self-employed	5 (6.80%)*	5 (6.30%)*
Not- paid	n.a.	n.a.
Student	n.a.	n.a.
Homemaker	17 (23.00%)*	12 (15.00%)*
Retired	29 (39.20%)*	57 (71.30%)*
Employed (but able to work)	2 (2.70%)*	1 (1.30%)*
Employed (unable to work)	n.a.	n.a.
Smoker - yes/total (%)	15/74 (20.30%)	10/80 (12.50%)
PC use	13 (17.60%)*	2 (2.5%)*
Mobile phone use	41 (55.40%)*	23 (28.80%)*
Alcohol		
Daily	3 (4.10%)	5 (6.30%)
5-6 day/week	3 (4.10%)	1 (1.30%)
3-4 days/week	1 (1.40%)	3 (3.80%)
1-3 days/month	13 (17.60%)	5 (6.30%)
Less than once/month	53 (71.60%)	66 (82.50%)

*Statistically significant difference between intervention and control groups.

Image 5: Outcomes

Outcome		Intervention			Control	
	Baseline Mean (standard deviation) (SD)	After 12 month Mean (SD)	p-value	Baseline Mean (SD)	After 12 month Mean (SD)	p-value
HbA1c (%)	8.551 (1.38)	7.141 (0.61)	0.000	8.621 (1.43)	7.771 (0.78)	0.000
SF36-PSC scores	52.019 (4.34)	53.197 (2.97)	0.053	50.994 (6.12)	49.734 (5.08)	0.001
SF36-MSC scores	50.046 (8.42)	53.508 (6.54)	0.000	48.194 (10.17)	44.952 (8.90)	0.000
PAID scores (decrease denoted improvement)	17.698 (13.14)	10.793 (12.90)	0.000	22.013 (13.9)	26.363 (12.54)	0.000
IPAQ scores (MET-minutes/week)	7030.79 (5341.31)	7929.84 (5245.59)	0.008	6939.58 (6628.94)	4664.83 (4515.02)	0.000
KID-MED adapted for adults scores	0.24 (0.42)	0.16 (0.36)	0.096	0.16 (0.36)	0.06 (0.24)	0.008

Image 6 Ancillary Analysis

Outcome	Mean difference between group (95% Confidence Interval)	p-value
HbA1c (mmol/mol)	**-6.13 (-10.45 to -1.81)**	**0.001**
Total Cholesterol (mg/dl)	**2.41 (-13.6 to 18.46)**	**0.765**
Low-density lipoprotein (mg/dl)	**6.72 (-2.57 to 16.02)**	**0.155**
Triglyceride (mg/dl)	**12.90 (-24.17 to 49.97)**	**0.490**

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