EFFECTS OF SMARTPHONE APPLICATION FOR THE SELF-MANAGEMENT OF DIABETES: A RANDOMIZED CONTROLLED TRIAL IN BANGLADESH CONTEXT

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Background

DIABETES BURDEN: GLOBAL

10.5% in 2021	Prevalence →	15.3% in 2045
$966 billion in 2021	Cost →	$1 trillion in 2030

DIABETES BURDEN: BANGLADESH

14.2% in 2021	Prevalence →	15.3% in 2045
$1,005.4 million in 2021	Cost →	$1,390 million in 2045

Source: Bangladesh Bureau of Statistics, 2020; IDF Diabetes Atlas Tenth Edition 2021

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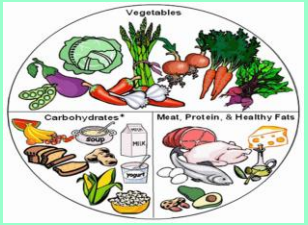
Background…

WHAT CAN BE DONE?

For healthy people, diabetes can be prevented

For diabetic patient, it can be managed by 7 self-management components

DRUG



DIET

PHYSICAL EXERCISE

FOLLOW-UP VISIT

AVOID TOBACCO

BLOOD GLUCOSE TEST

FOOT CARE

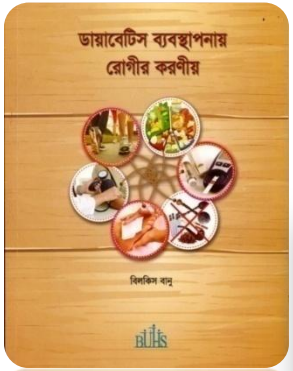
Source: Adapted from the Summary of Diabetes Self-care Activities (SDSCA)]

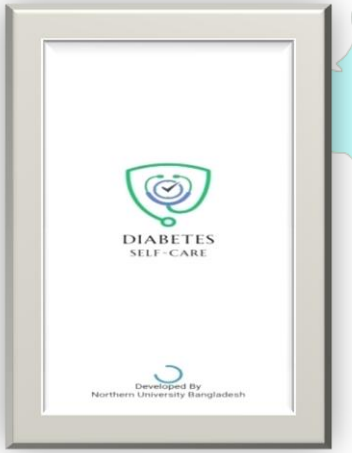
Justification

TO IMPROVE KNOWLEDGE, ATTITUDE & SELF-MANAGEMENT PRACTICE

Traditional Method

Educational & Behavioral Intervention





M-Health

Continuous Reminder & Monitoring

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Ref: BTRC 2017 & 2022

Justification (Continuation of previous works) & Objective

1. **Banu B,** Barnighausen T, Sauerborn R, Souares A. Perceptions regarding smart phone application for the self-management of diabetes: A qualitative study in comprehensive approach. (under development)
2. **Banu B,** Ko KC, Khan MH, Ali L, Barnighausen T, Sauerborn R, Souares A. Effects of traditional versus m-Health educational interventions for diabetic patients: a randomised controlled trial in peripheral district of Bangladesh. Diabetes Epidemiology and Management. 2023 Jan 1; 9: 100106. Doi: https://doi.org/10.1016/j.deman.2022.100106
3. **Banu B,** Khan MMH, Ali L, Barnighausen T, Sauerborn R, Souares A. Predictors of non-adherences to diabetes self-management recommendations among patients in peripheral district of Bangladesh. 2023. (Under Review).
4. Yasmin F, Nahar N, **Banu B,** Ali L, Sauerborn R, Souares A. The influence of mobile phone-based health reminders on patient adherence to medications and healthy lifestyle recommendations for effective management of diabetes type 2: a randomized control trial in Dhaka, Bangladesh. BMC Health Services Research. **2020** Jun 8; 20(1):520. doi: 10.1186/s12913-020-05387-z.
5. Yasmin F, Ali L, **Banu B,** Rasul FB, Sauerborn R, Souares A. Understanding patients' experience living with diabetes type 2 and effective disease management: a qualitative study following a mobile health intervention in Bangladesh. BMC Health Services Research **2020** Jan 9; 20(1):29. doi: 10.1186/s12913-019-4811-9.
6. Yasmin F, **Banu B**, Zakir S, Sauerborn R, Ali L, Souares A. Positive influence of short message service and voice call interventions on adherence and health outcomes in case of chronic disease care: a systematic review. Medical Informatics and Decision Making.**2016**, 16:46. doi: 10.1186/s12911-016-0286-3.

Objective: To assess the effectiveness of Smart Phone Application 'Diabetes Self-Care' for the self-management of diabetes

Methods

STUDY TYPE & DESIGN Randomized Controlled Trial (RCT)

STUDY PERIOD 01 Year (July 2022 to June 2023)

STUDY PLACE Dhaka District of Bangladesh

Savar Swasthoseba Kendro, NHN
For Intervention Group

BIHS General Hospital, Mirpur
For Control Group

Hospitals affiliated with Diabetic Association of Bangladesh

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Methods…

SAMPLE SIZE

- 400 adult diabetic patients were considered with 200 in each group
- the formula "n='[2 X $(a+b)^2$ X $\mho^2$]/ $(\mu1-\mu2)^2$" *
- a (conventional multiplier for alpha, 0.05) = 1.96
- b (conventional multiplier power)= 0.842
- $\mho$ (population variance)=16.3
- ($\mu1-\mu2$) (population mean difference among two groups)= 4.57
- detected with 80% power and 0.05 significance level

SAMPLING TECHNIQUE

- Participants were selected randomly from the patient register provided by the selected hospitals.
- Considered inclusion criteria.

* Das S, Mitra K, Mandal M. Sample size calculation: Basic principles. Indian Journal of Anaesthesia. 2016 Sep;60(9):652

Methods…

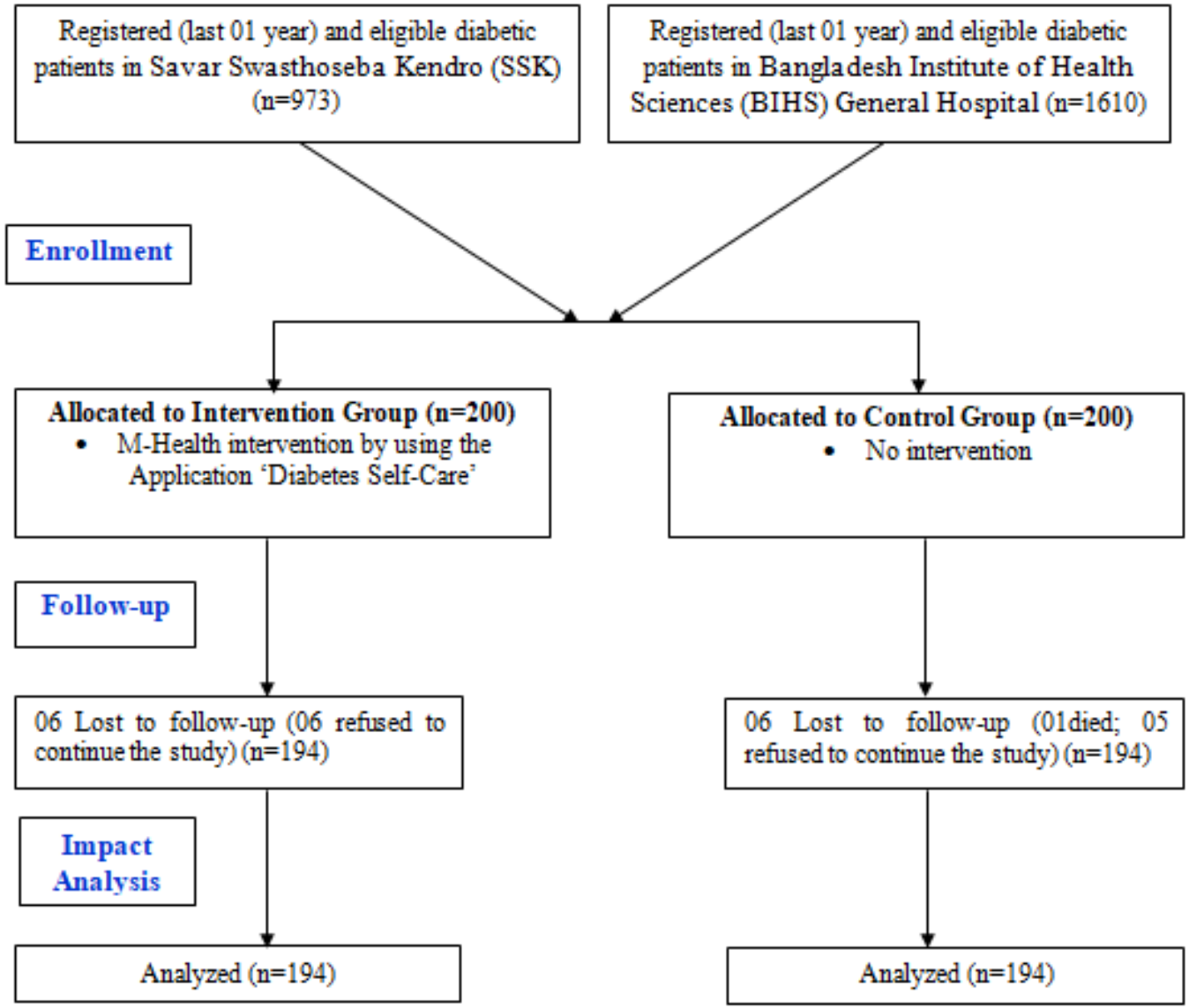
STUDY PARTICIPANTS

- Diabetic patients aged 18-64 years
- Residing within 2 km of study places (selected hospitals)
- Having smartphone
- Willingness to participate in this study
- Without GDM/mental/physical disability

STUDY INSTRUMENT

- Pre-tested and semi-structured questionnaire included
  - Basic and technical knowledge of diabetes
  - Adherence to 7 self-management components
  - socio-demographic, disease, therapeutic, health services and clinical characteristics

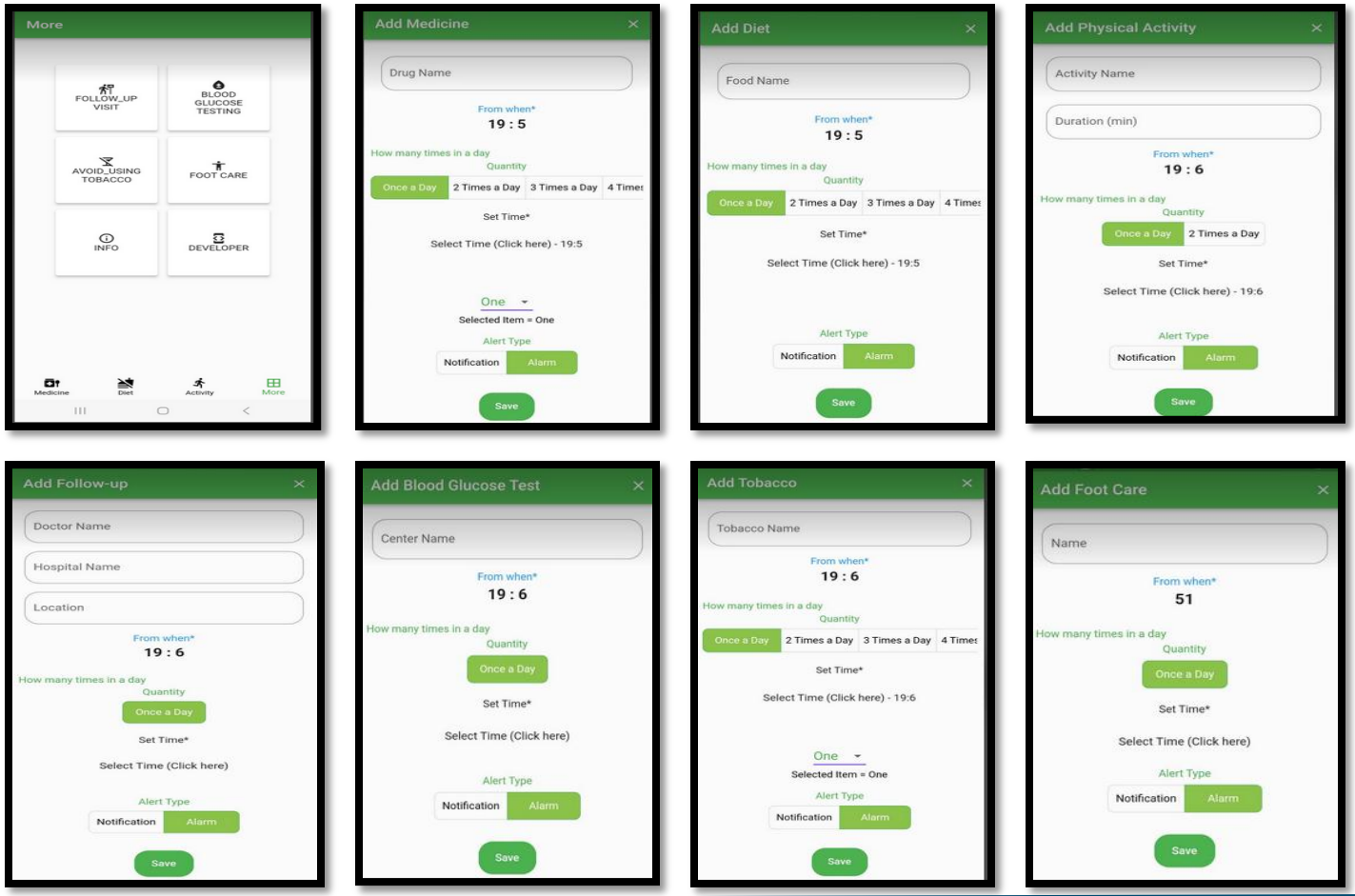
Methods…(Flow of the participants throughout the study)



Methods…

INTERVENTION MATERIAL

- ‘Diabetes Self-Care’ Application



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Methods… How the App works

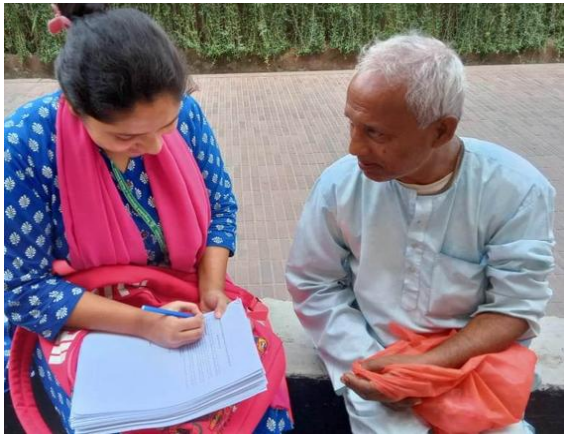
Components	Enter the advices provided by the health care providers
Drug 	Name, Dose, Frequency, Direction, and Duration
Diet 	Frequency, Types and Quantity of Foods
Physical exercise 	Name, Timing and Duration
Follow-up visit 	Date and interval between 2 visits
Tobacco avoidance 	Tobacco name and usual timing to take
Blood glucose test 	Date and interval between 2 diagnosis
Foot care  	Feet wash & Inspection, Shoe & Sock Inspection, Toenails Trim

The Application will remind according to the advices

Methods…

DATA COLLECTION METHOD

- Face-to-face interview



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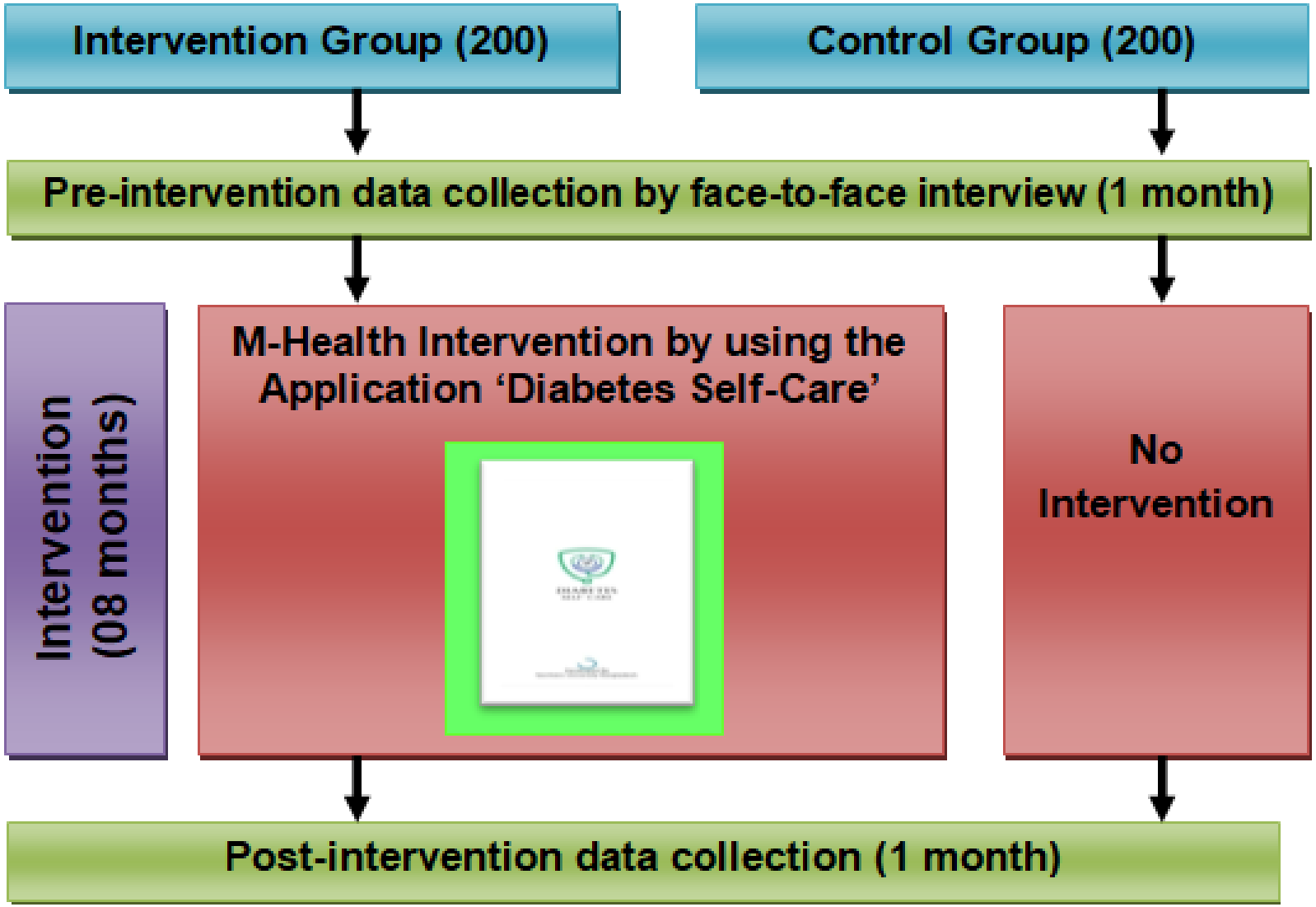
Methods…(Study Process)



Methods…(Analysis)

- Software: SPSS
- Techniques: Frequency (percentage), mean±SD, t-test, McNemar's test and logistic regression.

7self-management components	Measuring definitions of adherence
Drug	Total score: ≤99% (follow dose, direction, duration, frequency of drug intake prescribed by the physician).
Diet	Taking at least 5 meals/ day.
Physical Activity	Daily at least ≥150 minutes/ week.
Risk Behavior	Currently not taking any kind of tobacco products.
Blood Glucose Test/ Follow-up visit	Diagnosed blood glucose /went follow-up visit within 7 days according to advised date by the physician.
Foot care	Follow basic foot care principles

Results

Table 1: Baseline characteristics of the study participants

	Total (388)		Intervention Group (194)		Control Group (194)		p-value
	Mean±SD or n (%)		Mean±SD or n (%)		Mean±SD or n (%)		
1. Gender[a]							0.14
Male	158	40.7%	86	44.3%	72	37.1%	
Female	230	59.3%	108	55.7%	122	62.9%	
2. Number of children[b]	3±2		3±2		3±2		0.53
3. Family size[b]	4±2		4±2		4±2		0.06
4. Family history[a]							0.26
Had	223	57.5%	117	60.3%	106	54.6%	
Didn't have	165	42.5%	77	39.7%	88	45.4%	
5. Used therapy[a]							0.82
Clinical (oral drug/ insulin)	367	94.6%	183	94.3%	184	94.8%	
Others (herbal/ homeopath)	21	5.4%	11	5.7%	10	5.2%	
6. Distance to go to hospital[a]							0.55
<3 Kilometer	293	75.5%	144	74.2%	149	76.8%	
>3 Kilometer	95	24.5%	50	25.8%	45	23.2%	
7. Cost to go to hospital[a]							0.75
<0.74 USD	241	62.1%	122	62.9%	119	61.3%	
>0.74 USD	147	37.9%	72	37.1%	75	38.7%	
8. Accompanying person needed[a]							0.76
Yes	217	55.9%	107	55.2%	110	56.7%	
No	171	44.1%	87	44.8%	84	43.3%	
9. Blood Pressure (diastolic)[b]	81.25±13.39		81.16±11.53		81.35±15.05		0.89
10. Blood Glucose (fasting)[b]	8.29±2.91		8.22±2.80		8.36±3.003		0.65

[a] data presented as proportion (n) and percentage (%); [b] data presented as mean ± SD; Statistical significance at $p<0.05$; n for each group (Intervention and Control) = 194;

Results…

Table 2a: Changes in knowledge and differences between groups after the intervention

Knowledge on different components of diabetes and diabetes management	Intervention Group (n=194)			Control Group (n=194)			Differences between intervention vs. control group (at end line)
	Baseline	End line	p	Baseline	End line	p	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD		p
1. Total Basic Knowledge	15.90±10.85	26.38±10.41	0.01*	16.63±11.18	17.17±11.52	0.06	0.01*
2. Drug	25.43±27.88	48.63±35.07	0.01*	28.35±28.75	27.75±29.07	0.21	0.01*
3. Diet	38.98±26.42	53.16±24.18	0.01*	40.34±26.14	38.72±26.98	0.13	0.01*
4. Physical Exercise	16.32±15.80	34.77±19.05	0.01*	16.72±15.35	17.30±15.75	0.19	0.01*
5. Follow-up visit	8.56±15.33	22.89±29.57	0.01*	9.69±16.44	9.79±16.81	0.56	0.01*
6. Foot care	12.44±15.55	54.57±45.05	0.01*	13.14±16.03	12.18±15.81	0.05	0.01*
7. Total Technical Knowledge	21.13±14.70	43.91±19.13	0.01*	22.14±14.18	21.62±15.49	0.27	0.01*
8. Total Knowledge on Diabetes	17.88±11.11	33.02±11.67	0.01*	18.72±11.51	18.86±12.06	0.68	0.01*

Data are presented as mean±Standard deviation. A paired t-test was used for within-group comparisons and an independent t-test was used for group comparisons,with a significance level of p* <0.05. Adjusted for gender, number of children, family size, family history, used therapy, distance to go to hospital, cost to go to hospital, accompanying person needed, blood pressure (diastolic), and blood glucose (fasting).

Results…

Table 2b: Knowledge (mean) differences between groups after one-year intervention

Parameter (Knowledge on different components of Diabetes)	Differences between groups (at endline)		
	Intervention Group (mean)	Control Group (mean)	Differences (mean) with significance
1. Total basic knowledge on diabetes	26,38	17,17	**9,21***
2. Drug	48,63	27,75	**20,88***
3. Diet	53,16	38,72	**14,44***
4. Physical exercise/ activities	34,77	17,3	**17,47***
5. Follow-up visit	22,89	9,79	**13,1***
6. Foot care	54,57	12,18	**42,39***
7. Total technical knowledge	43,91	21,62	**22,29***
8. Total knowledge on Diabetes	33,02	18,86	**14,16***

ANCOVA (Bonferroni) was used between-groups comparisons, with a significance level of p* <0.05.

Results…

Table 3: Changes in adherence and differences between groups after the intervention

Adherence to different components of diabetes management	Intervention Group (n=194)			Control Group (n=194)			After the intervention
	Baseline	Endline	p	Baseline	Endline	p	Odd ratio (95% CI)/p
	n (%)	n (%)		n (%)	n (%)		
1. Drug	83 (42.8)	163 (84.0)	0.01*	87 (44.8)	102 (52.6)	0.01*	4.74 (2.94-7.63)/ 0.01*
2. Diet	86 (44.3)	164 (84.5)	0.01*	89 (45.9)	92 (47.4)	0.54	6.06 (3.74-9.80) 0.01*
3.Physical exercise	50 (25.8)	139 (71.6)	0.01*	58 (29.9)	63 (32.5)	0.23	5.25 (3.40-8.10) 0.01*
4. Follow-up visit	49 (25.3)	127 (65.5)	0.01*	54 (27.8)	58 (29.9)	0.21	4.44 (2.90-6.81) 0.01*
5. Blood glucose test	71 (36.6)	138 (71.1)	0.01*	78 (40.2)	84 (43.3)	0.10	3.22 (2.11-4.91) 0.01*
6. Tobacco use	150 (77.3)	167 (86.1)	0.01*	138(71.1)	138(71.1)	1.00	2.51 (1.50-4.18)/ 0.01*
7. Foot care	72 (37.1)	146 (75.3)	0.01*	81 (41.8)	86 (44.3)	0.06	3.82 (2.48-5.88) 0.01*
8.Total adherence	88 (45.4)	172 (88.7)	0.01*	86 (44.3)	96 (49.5)	0.01*	7.98 (4.71-13.49) 0.01*

Data are presented as proportion; n (percentage%). McNemar test was used within-group comparisons and LogisticRegression was used between-group comparisons after one-year intervention with a significance level of p* <0.05. The adherence level of each parameter was indicated. The Control Group was the reference category for calculating the Odds ratio. Adjusted for gender, number of children, family size, family history, used therapy, distance to go to hospital, cost to go to hospital, accompanying person needed, blood pressure (diastolic), and blood glucose (fasting).

Results…

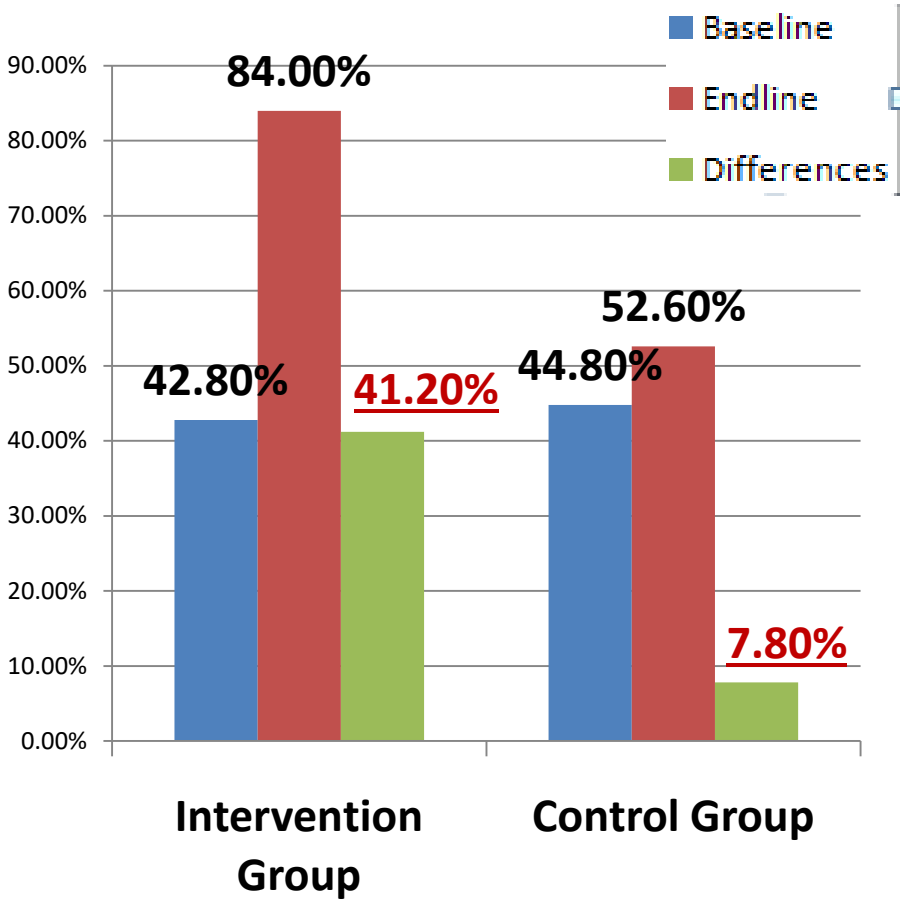


Figure 1 : Changes in drug adherenceafter the intervention

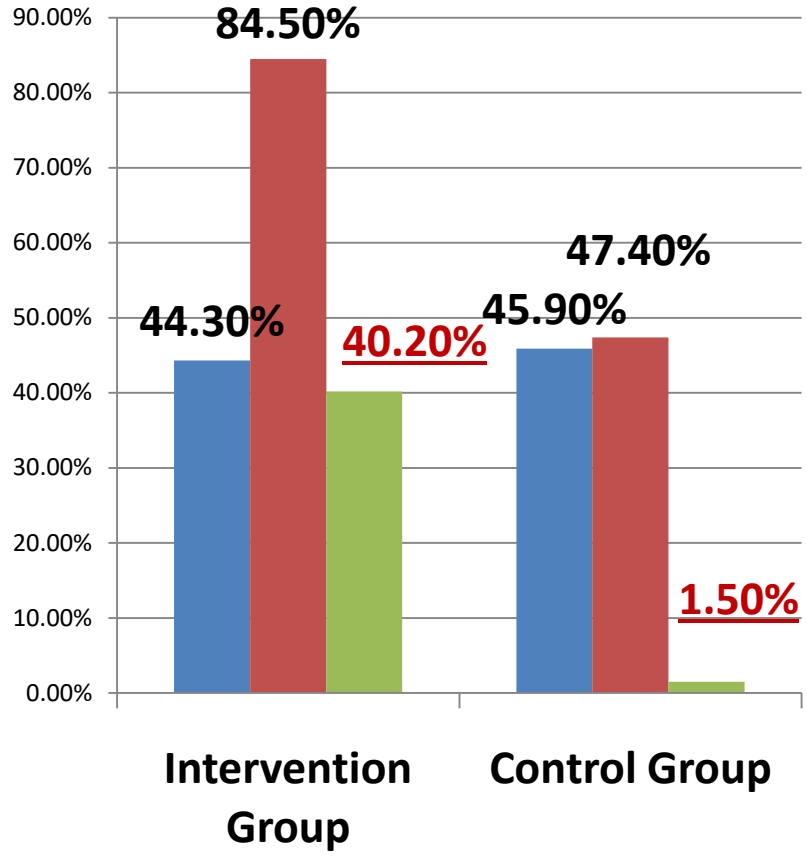


Figure 2: Changes in dietary adherence after the intervention

Results…

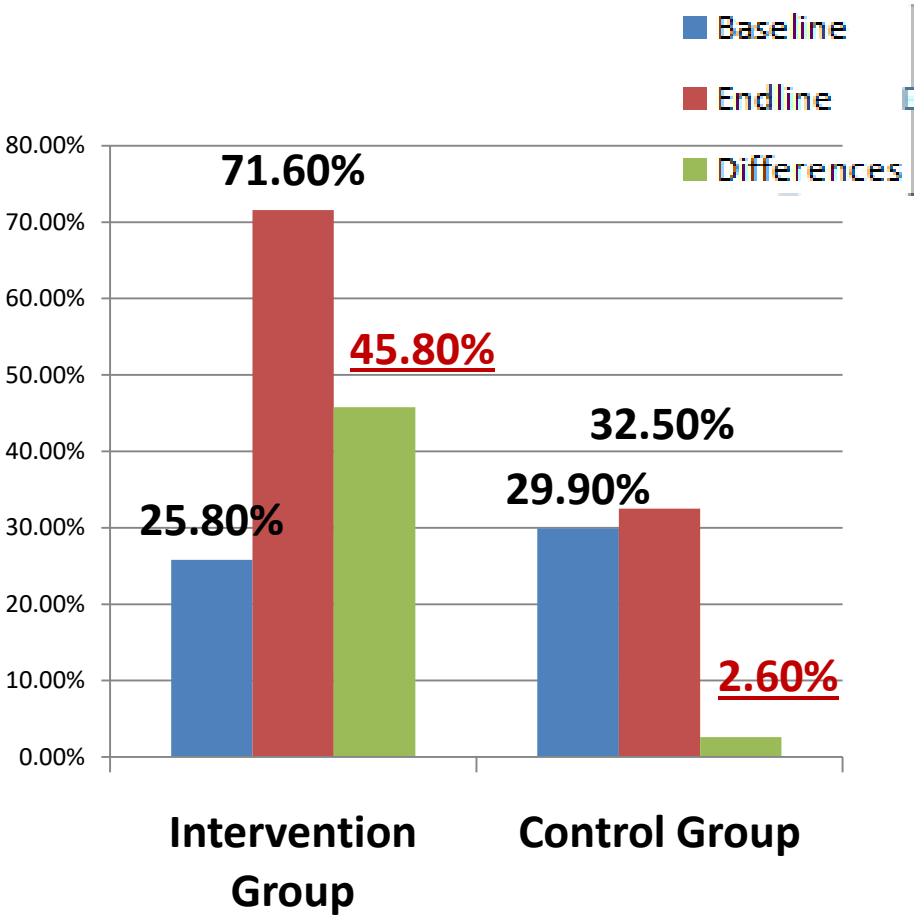


Figure 3 : Changes in physical exercise adherence after the intervention

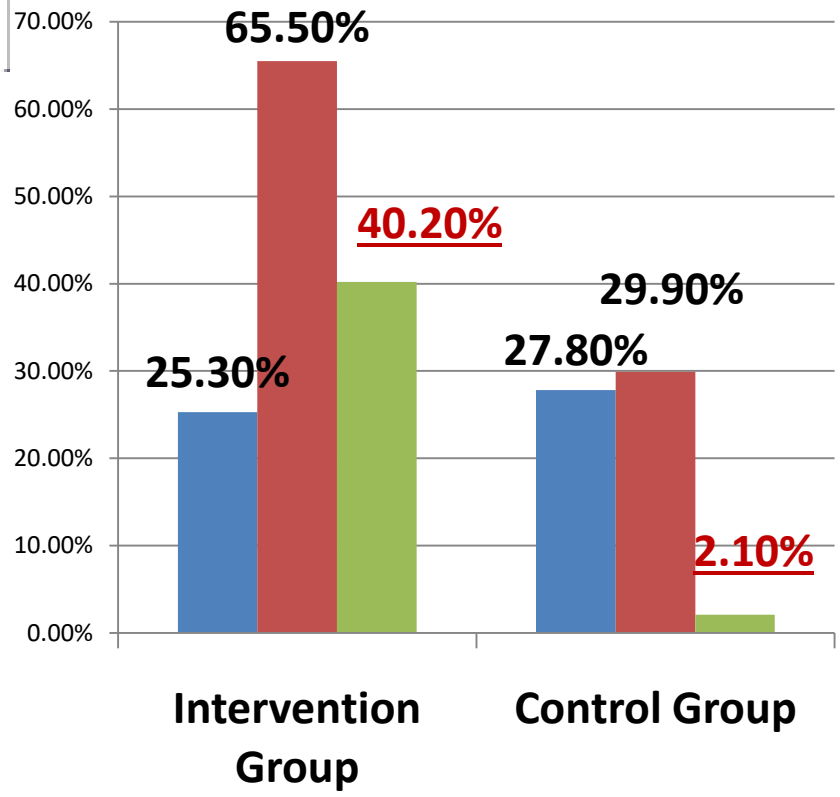
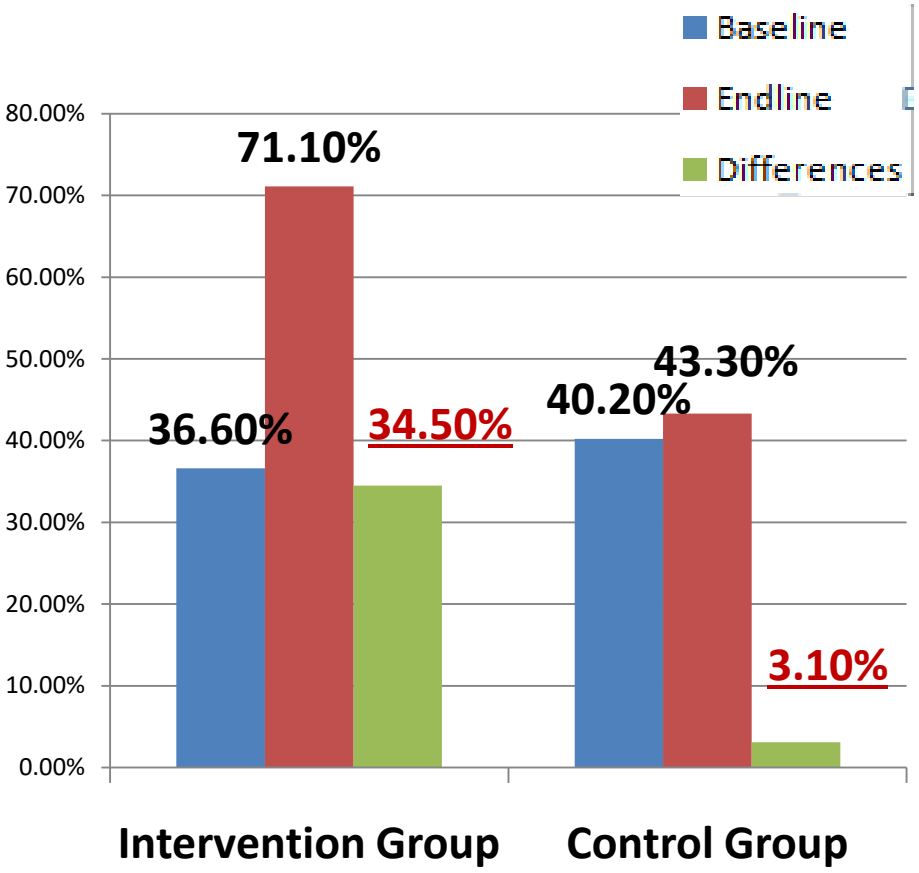


Figure 4: Changes in follow-up visit adherence after the intervention

Results…



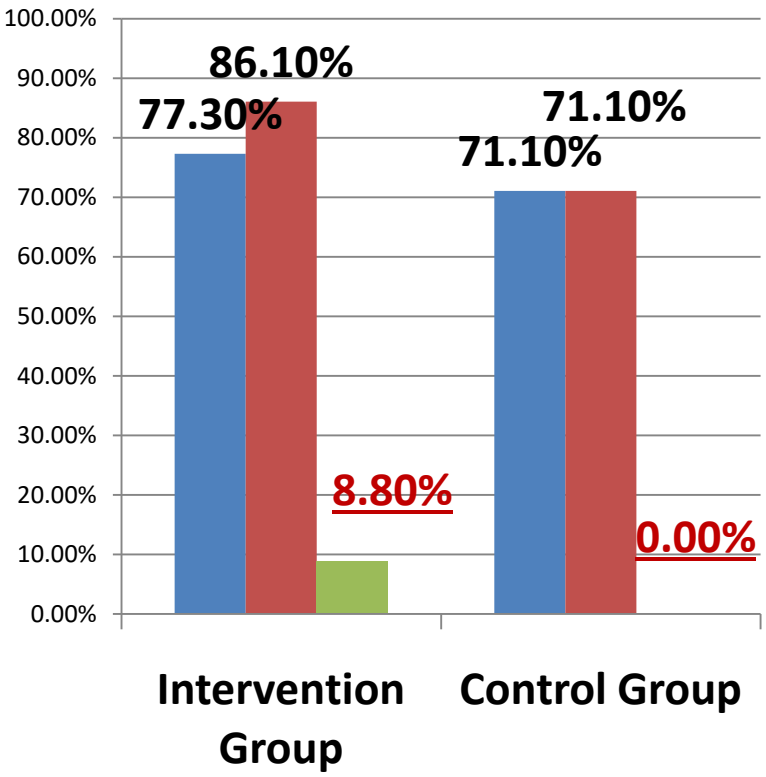


Figure 5 : Changes in blood glucose test adherence after the intervention

Figure 6: Changes in tobacco use adherence after the intervention

Results…

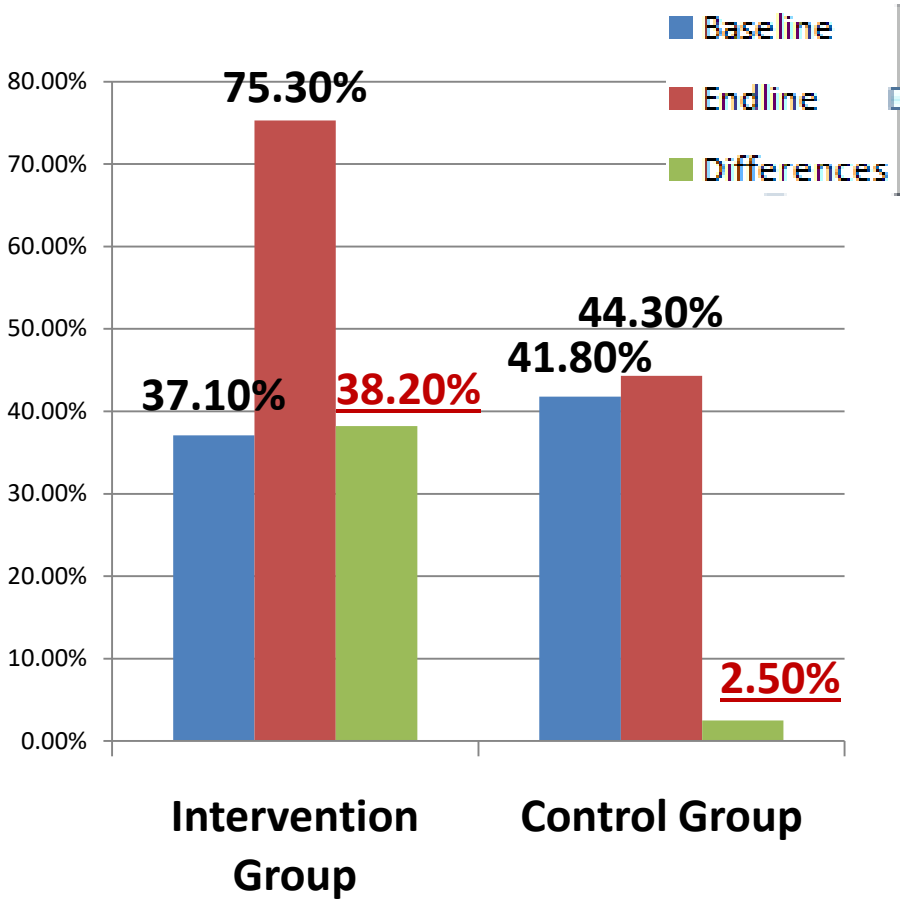


Figure 7 : Changes in foot care adherence after the intervention

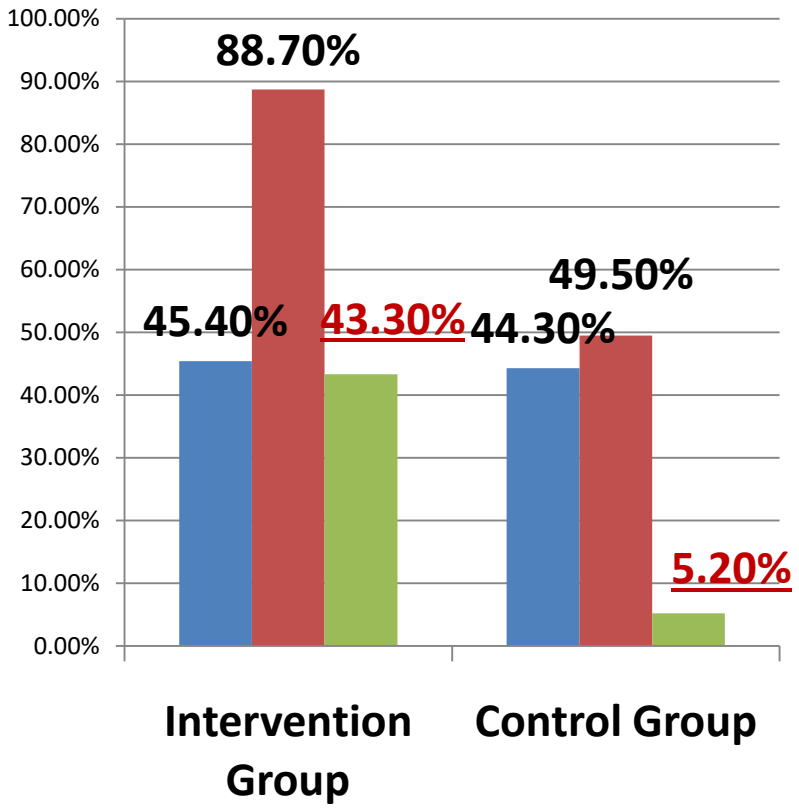


Figure 6: Changes in Total adherence after the intervention

Conclusion & Recommendation

- The study showed a significant improvement and positive impact of the m-Health intervention by using smart phone application on patients´ knowledge and adherence on seven self-management components of diabetes.
- These types of interventions could be replicated for the self-management of diabetes for the global diabetic patients and other non-communicable diseases.

Acknowledgements

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