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Effectiveness of Mobile App-Assisted Self-Care Interventions on lifestyle and laboratory indices in Non- Alcoholic fatty liver: A Randomized Controlled Trial

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Abstract

Background: Smartphone application interventions are helpful tools to improve self-care of patients with chronic diseases such as Non-alcoholic fatty liver disease (NAFLD). A mobile app-assisted self-care interventions were developed for patients with NAFLD then a randomized controlled trial was conducted to examine its effectiveness on lifestyle and laboratory indices.

Methods: A randomized clinical trial done on the 68 NAFLD Patients. They were assigned randomly in two Control and Intervention groups. Self-care application was developed and implemented for Intervention group about 3 months. Data were gathered by lifestyle questionnaire. It was completed before, one, two and three months after the intervention by patients of both groups. Before and after intervention lipid profile, liver function tests, FBS and CBC of patients were measured. Telephone follow-up was performed. Data was analyzed using SPSS16 software and chi-square, T tests, variance with repeated measures and MacNemar' statistical tests.

Results: Average of lifestyle score one (p=0.017), two (p=0.001) and three (p=0.001) months, Chol (p=0.008), insulin (P<0.001) and HOMA index (p=0.008) in both groups had a significant difference after using application as intervention. Although, there was significant difference in lifestyle in both control (CG) (p<0.001) and experimental group (EG) (p<0.001) after the intervention. In the EG, there was a statistically significant difference in TG (p=0.008), Chol (p=0.001), HDL(p=0.001), LDL(p=0.004), insulin(p=0.008), AST(p=0.039) and ALT (p =0.002) and while in the CG in terms of FBS(p=0.013), ALT(p=0.016) after the intervention.

Conclusion: Employing self-care application could improve lifestyle and liver laboratory indicators in NAFLD patients and can be used as part of health promotion programs for these patients. Nowadays, using such applications routinely can promote self-care of chronic patients.

Trial Registration: Current Controlled Trials is IRCT20190518043614N1 and the date of registration is 2019-06-15 (https://fa.irct.ir/user/trial/39610/view).

Keywords: Mobile Application, Self-care, Lifestyle, Non-alcoholic fatty liver disease

Introduction

Non-alcoholic fatty liver disease (NAFLD) is the main driver for increased chronic liver disease incidence (1). Approximately 25% of the world's population are affected by NAFLD and it is increasing globally due to the global obesity epidemic (2). In a meta-analysis study by Moghaddasifar et al (2016), NAFLD prevalence among Iranian people was estimated at 33.9% (3). It is currently the fastest growing indication to liver transplantation both in United States and Europe (4). In fact, NAFLD is a preventable and treatable (2).

Currently, for NAFLD treatment no Food and Drug therapies are approved but lifestyle interventions are the most established treatments. weight loss measures including of reducing the intake of fatty, high-sugar, and high-carbohydrate foods, increasing physical activity, and

reducing sedentary time (2). For reversing NAFLD, self-care management requires by patients, but patients are not well skilled with necessary knowledge tools and support (5). Technology including mobile app-assisted interventions facilitate patient–care provider communication, information exchange, health literacy, decision making, and peer support, without the constraints of time and geography (6). Orem, a self-care theorist in nursing, argue that self-care is a learnable skill and standard way, through which many needs of patients in cases of sickness or poor health can be addressed that enables people to have a more active role in self-care (7).

Telenursing conveys large amounts of information within a short time and provides patients with the opportunity to find answers to their questions at home and increase adherence to healthy diet (8). One of the tele-nursing methods is the use of smartphones, through which the patient can self-monitor his/her lifestyle choices and health-related while given feedback based on his/her condition to correct the behavior (1). The use of smartphones and their apps has provided grounds for higher access to caring tools by health-care professionals, which can used to improve the symptoms of the disease as well as offering educational contents for clients in self-care ((2). Health-related apps are capable of improving overall community health by measuring health parameters at low cost, the contributions of which can be effective in the management of chronic diseases (3).

Previous research indicates the efficacy of mobile apps for lifestyle changes (8, 9, 10). The findings of a study by Akbar et al (2020) showed that most of the health-oriented apps lack scientific content based on scientific theories (11). Researchers have recommended integrating theory in the development of health-oriented apps that improve health outcomes (12).

Evidence suggests that lifestyle modification, especially in NAFLD patients, results in more favorable clinical outcomes along with promotion of health in the society (13). Providing self-care education to patients with the purpose of altering their behavior plays a key role in changing the lifestyle of NAFLD patients. Therefore, developing an Iranian app that can also provide up-to-date training courses based on reliable scientific sources and nursing theories with the purpose of improving lifestyle behaviors for NAFLD Iranian patients in Persian language can be an effective and resourceful tool in improving lifestyle and alleviating patients' health complications. Therefore, the present study was performed with the purpose of determining the effect of self-care app on lifestyle and laboratory parameters of patients with NAFLD.

Methods

This is a parallel unblinded randomized clinical trial with 1:1 allocation ratio. The intervention was using a self-care application that examined the patient's conditions and provided necessary recommendations along with telephone follow-ups. Effect of this application on the lifestyle and laboratory indicators of patients with NAFLD was monitored. Based on standard deviations from a prior study by Gharachourlo et al (14), the sample size was calculated to detect a 10-point difference (d = 10) in lifestyle scores between groups. Assuming a 95% confidence level (α= 0.05) and 80% power (β= 0.20), 31 participants per group were required. To account for a 20% anticipated dropout rate, the final target was adjusted to 37 participants per group (N = 74 total).

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \times (\sigma_1^2 + \sigma_2^2)}{d^2}$$

$$z_{0.975} = 1.96, z_{0.8} = 0.84, d = 10, \sigma_1 = 12, \sigma_2 = 16$$

Finally, 68 patients with NAFLD who referred to the gastrointestinal clinic of Imam Khomeini Hospital in Tehran, Iran were included in the study. To prevent the exchange of information between the control and Intervention Group, the simple random allocation method was used to assign separate sampling days for the Intervention and control groups. For this purpose, two cards labeled A and B were considered for CG and EG (card A for patients in the CG and card B for patients in the EG) and for determining sampling days two cards labeled a and b were considered (card a for even days and card b for odd days of the week). A draw was made between the cards. In the group selection, card A was obtained, and card b was obtained for sampling day. Hence, control group was to be sampled on odd days while Intervention group was to be sampled on even days. Then, according to the even or odd day, the available samples were examined for inclusion criteria and entered the study according to the sampling day by researcher (figure 1). No changes were occurred to the trial after it commenced.

Tree part instrument including demographic and disease data, and the LSQ (lifestyle questionnaire) were used for data collection. The LSQ had 32 items and six dimensions including physical health and disease prevention, exercise and health, nutrition and weight control, psychological health, social health, avoidance of drugs and alcohol, which were scored using a Likert scale, which were graded as always (3), usually (2), sometimes (1) and never (0). The LSQ tool was prepared and validated by Lali et al. in 2009 and its' reliability of the tool was used using the method of internal consistency and retesting. Cronbach's alpha coefficients in the internal consistency method are between 0.76 and 0.89, and in the retest method, the reliability coefficients are between 0.84 and 0.94 (15).

Inclusion criteria:

The inclusion criteria were consisted of definitive diagnosis of NAFLDL(grade one to four) by a Gastroenterologist, BMI>25, confirmation the ability of patient to perform moderate physical activity by a specialist physician, aged between 19 to 60 years, access and ability to work with an android smartphones, desire to use smartphones on a daily basis, lack of hearing, vision and speech problems, consent and interest in participating in the study, not suffering from liver diseases such as viral, autoimmune or drug hepatitis, Wilson disease, hemochromatosis, hyperthyroidism or hypothyroidism, gallstones, gallbladder cancer, diabetes, obesity due to high corticosteroids intakes, Cushing's syndrome, Addison's disease, chronic infections such as tuberculosis, genetic diseases related to fat disorder, not taking hepatotoxic drugs during the last 6 months, non-exposure to petrochemicals and non-consumption of alcohol and drugs.

Exclusion criteria:

Exclusion criteria were consisted of not using the self-care application for one month during the intervention by the experimental group, not answering the phone during follow-up, not visiting the clinic for two consecutive months in the control group, and being diagnosed with hepatitis during the study.

Application design:

Guidelines and reliable sources of medicine and nursing in disease management, nutrition, sports and life skills were used to prepare the content of the application. In order to properly provide self-care training, Orem's self-care model and behavioral therapy strategies were used. In order to check the validity of the content of the application, the prepared content was given to ten faculty members of gastroenterology and nursing who had an experiences of treating and caring for people with liver diseases, then the necessary corrections were applied. Also, the vice-

chancellor of Virtual Medical Sciences University, who works in virtual and hybrid education, and the consultant professor of application design, were asked to approve the items. Then the initial template of the application and the flowchart of each page and the connection of the pages were drawn. The final draft and features of the application were designed and coded with the Android operating system and implemented on the smartphone. The researcher used the application on a trial basis for two weeks and made the necessary corrections. The application was installed on the phones of ten patients with NAFLD and was used by the patients on a trial basis for one month. Opinions of the patients were summarized in terms of usability, then application was modified again. Then the content reliability was evaluated through 10 NAFLD patients and the reliability was 0.98.

Application features:

1. Being interactive

2. Security by creating a password for each person (Figure 2)

3. Evaluating the user's lifestyle and giving feedback to the user by sending a dedicated self-care training text (Figures 3, 4, 5)

4. Calculation of the user's body mass index after recording height and weight information (Figure 6)

5. Targeting ability to reduce the user's weight (Figure 7)

6. Calculation of the daily calorie requirement of the user

7. Sending a reminder message to user, if calories are not recorded by 22:00 every night

8. Sending two educational and motivational messages daily

9. The possibility of establishing a relationship between the patient and the researcher

10. The possibility of separating harmful and useful foods through coloring (Figure 8)

11. Persian language of application for Iranian users

Phase 1: Patients that were diagnosed with NAFLD by Gastroenterologist, entered to the study according to the inclusion criteria. The goals of the project were explained to the patients and written consents were obtained from them. The samples were divided into two groups of control and experimental through random allocation. Height, weight and body mass index of patients were measured. Instructive pamphlets on NAFLD and self-care were delivered to both groups. Patients were given a lifestyle questionnaire to complete and were referred to the laboratory to be tested for ALT, AST, TG, Chol, HDL, LDL, FBS, Alb, ALKph, CBC, HOMA index.

Lifestyle questionnaires were completed by patients before the intervention, 1, 2 and 3 months after the intervention in both groups. Based on the responses of patients in both groups to the questionnaire, their educational needs and self-care issues were identified each time and they received the required instructions. Simultaneously, patients' weight loss, lifestyle changes and adherence to the treatment were examined in person at the gastrointestinal clinic or by telephone (weekly for the first month, every two weeks for second and third months).

Phase 2: For the experimental group, the fatty liver self-care app was installed on the patients' smartphones and they were instructed practically on how to use it. Then patients' information includes of height, weight and age were inputted in the information registration section of the

app. Then, the body mass index (BMI) was automatically calculated by the application. Patients set a weight reduction goal for the first month. Intakes Calories from eaten food and spent time on physical activity are asked by app to be entered daily. Missing data resulting from participant dropouts were handled using a per-protocol analysis framework, and only participants with complete post-intervention data were included in the final analysis.

WhatsApp messenger was installed for all patients in the experimental group. An interactive group was formed. Hence, a patient could ask their questions and clarify ambiguities personally in PV or voice their concerns in the relevant group. The intervention was performed for patients in the experimental group during 12 weeks. After 12 weeks, the lifestyle questionnaires were again completed by both groups and the liver laboratory indices of patients in both groups were also evaluated. pamphlets and clinic follow-ups given to both groups. No adverse events or app-related technical stress were tracked. The trial was ended because it reached its planned sample size completion. Data of both groups before and after the intervention were analyzed using SPSS v.16. In the descriptive statistics section, tables for frequency distribution, mean and standard deviation were employed, while for the purposes of the inferential statistics, Fisher's exact and chi-square tests, independent t-test and repeated measures analysis of variance, MacNemar and Kolmogorov-Smirnov, were used. No additional subgroup or sensitivity analyses were pre-specified or performed.

This study adheres to the CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting randomized controlled trials (16). A completed CONSORT checklist has been provided as an additional submission file (17).

Results:

The results related to the demographic characteristics of the sample population revealed that most of the participants in both groups were females. Average age of the control and intervention group were 45.02 ± 10.45 and 41.74 ± 9.19. Most of the participants from both groups were married, and unemployed in the Control Group, while most were employed in the EG. Samples in the CG and EG were mostly high school and university graduates. The results of the disease information showed that most of the participants had grade 1 fatty liver and they had the disease for less than one year during the initial appraisal. No clinical harms, adverse events, or unintended negative outcomes were reported or observed in either the experimental or control group during the trial.

The results of independent t-test revealed that before the intervention, there was no statistically significant difference in terms of BMI between the CG and EG ($p=0.313$), but after the intervention, there was a statistically significant difference between them ($p=0.021$).

Before of the intervention the mean score of lifestyles in the two groups were not significantly different ($p=0.189$) but 1, 2 and 3 months after the intervention there was a statistically significant difference between groups ($p= 0.017, 0.001, 0.001$). Psychological health was statistically significant different before and after the intervention ($p= 0.010$) so that mean of psychological health score was higher in EG than CG before and after the intervention. Also, in physical health and disease prevention and avoidance of drugs and alcohol, there were not any significant differences before and after intervention between the groups. In exercise and health, nutrition and weight control and social health dimensions, before of the intervention no significant different were observed but after the intervention significant different were observed ($p<0.05$) (Tables 1).

Based on analysis of variance with repeated measures on lifestyle, the mean score of lifestyles in the CG all dimensions were statistically significantly different in at least one period from the others ($p<0.001$). Ben Feroni's two-by-two comparison indicated that there was a statistically significant difference between the mean score of life style at the beginning and three months later ($p<0.001$), which was lower at the beginning. Moreover, the mean score of lifestyles in the EG in all dimensions was also statistically significantly different in at least one period from the others ($p <0.001$). Ben Feroni's two-by-two comparison indicated that there was a statistically significant difference between the mean score at the beginning and three months later ($p<0.001$), which was lower at the beginning (Table 2).

The results of chi-square test showed that before the intervention ALT between the two groups had a statistically significant difference ($p=0.038$) and the percentage of participants in the normal range in the CG (73%) was higher compared to the TG (48.4%). But, based on the results of chi-square and Fisher's tests, other laboratory tests did not have statistically significant differences before the intervention between the groups (Table 2).

The results of liver indices at three months after the intervention revealed that serum Chol levels were at normal levels in 73% and 96.8% of the samples in the CG and in the EG (respectively), a difference which was statistically significant ($p=0.008$). Regarding serum insulin index, 51.4% were at abnormal levels in the CG while 93.5% had normal levels in the EG, the difference of which was statistically significant ($p<0.001$). Relating the HOMA index, there was a statistically significant difference between the two groups, as 73% of patients in the CG were at normal level, while a staggering 96.8% of the patients in the EG had normal levels ($p=0.008$) (Table 3).

Comparing liver laboratory indices in the CG, the results showed that there was a statistically significant difference in FBS (P=0.013) and ALT (P= 0.016) before and after the intervention (p = 0.013), which returned to normal levels after the intervention. The results from analyzing liver laboratory tests in the TG showed that there was a statistically significant difference in TG (P=0.008), Chol (P=0.002), HDL (P=0.001), LDL (P=0.004) insulin (P=0.008), AST (P=0.039), and ALT (P=0.002) before and after the intervention, which all returned to normal ranges after the intervention (Table 4).

Discussion:

This study was conducted with the aim of determining the effect of self-care app on lifestyle and laboratory parameters of Iranian patients with NAFLD. The language of this application is Persian and It is useful for Iranian users. It can be Multilanguage in the future for other countries' users. According to the results of the study, there was statistically significant difference in lifestyle in both CG and EG after the intervention and 1, 2, 3 months after intervention average of lifestyle score was increased respectively. Although, there was significant difference in lifestyle between CG and EG after the intervention. It means using self-care app promote lifestyle of NAFLD patients in terms of exercise and health, nutrition and weight control and social health. Regarding laboratory indices, average of Chol, insulin and HOMA index in both groups had a significant difference after the intervention. But in the EG, there was a statistically significant difference in TG, Chol, HDL, LDL, insulin, AST and ALT.

Smartphone apps have the capacity to facilitate behavior change and a cost-effective, easy to use method that can be made available to most people of the society is highly preferable (18). Health apps have this feature. The results suggested that there was no statistically significant difference

between the two groups in terms of BMI before the intervention. However, after the intervention, the two groups had a statistically significant difference in terms of BMI and the average BMI in both groups decreased after the intervention, but this decrease was greater in the EG. In other words, the implementation of measures in both groups had an effect on reducing BMI but this effect was more pronounced in the EG. Mateo et al. (2015) and Carter et al. (2011) revealed the efficacy of mobile apps on weight loss and reducing BMI. (7, 8). Hence, for prevention of fatty liver focusing on continuous decreasing BMI should be noted (19).

The findings of the current study revealed that the mean score for lifestyles in both CG and EG increased significantly three months after the intervention compared to before the intervention, while there was a statistically significant difference among the mean lifestyle scores of the both groups in one, two and three months after the intervention in favor of the EG. These results indicated that the use of self-care educational apps could have a corrective effect on the lifestyle of patients with NAFLD. The results of several studies that examined the effects of using mobile apps for cardiovascular patients, health promotion, physical activity and diet indicated their efficacy (20- 22). In contrast, Garcia-ortiz et al. (2014-2016) reported that mobile apps lack long-term effectiveness. This is perhaps owing to the fact that entering eating habits and physical activities in these app takes time which may be an obstacle for people who are particularly less motivated to change their habits and are not motivated enough to continue to work with the app, in turn leading to low adherence and poor behavior among app users (22).

The results indicated that the percentage of patients who achieved acceptable levels of FBS and serum ALT increased significantly after the intervention compared to before the intervention in the CG, although other laboratory indicators did not change significantly. However, education and follow-up via phone calls have been proven to be effective in improving laboratory

293 indicators. In this regard, Zou et al. (2018) reported that instructing patients with NAFLD
294 regarding nutrition and exercise reduces levels of ALT and HOMA index (23).

295 There was also a statistically significant increase in the percentage of patients whose indices of
296 TG, Chol, HDL, LDL, insulin, AST, and ALT achieved normal range following the intervention,
297 thus reaffirming the effect of developing self-care app on improving laboratory indicators.

298 Owing to the fact that the two groups had statistically significant differences in ALT before but
299 were not after the intervention and the two groups were statistically significant in terms of Chol,
300 insulin and HOMA index after the intervention, and considering that the percentage of patients
301 who achieved normal level in the TG was higher than the CG, it is safe to say that using self-care
302 app in improving liver laboratory indicators of patients with NAFLD was more effective than
303 simpler methods of instructing and follow-up via phone call. Studies conducted by Osborn et al.
304 (2017), Fu (2017), Wu (2016) and Sankaran et al. 2017) emphasized the installation and use of
305 mobile apps because it improved hemoglobin A1C ($p<0.001$) (24-27). Johnston et al. (2016)
306 examined the effects of interactive mobile app after 6 months of intervention, the results of
307 which revealed LDL decreased in both CG and EG, while there was a statistically significant
308 difference between the two groups in favor of the EG (28). Considering that, laboratory
309 indicators are themselves secondary outcomes that are highly informative in the follow-up and
310 are highly sensitive to other outcomes that are obtained through patient self-reporting, in case the
311 app leads to the improvement of laboratory indicators.

312 In the present study, a mobile app was developed based on Orem self-care model to assist users
313 in recognizing their self-care needs, based on data's the patients were provided with instructions
314 on how to modify their lifestyles. Goals setting, self-monitoring and self-reporting methods were

315 employed as means to motivate implementation and practice of trainings and lifestyle changes.
316 Follow-up on patients was established using phone calls every two weeks for three months and
317 the researcher's interactive communication with the EG through WhatsApp, where the patients
318 could discuss their problems and questions, and receive consequent feedbacks. As studies have
319 indicated that multiple interventions implement use self-regulatory methods such as goal- setting,
320 self-monitoring, and patient follow-up are more effective in changing health behaviors than
321 methods neglecting them (18). This shows that the use of multiple strategies and continuous
322 interaction with patients is the key to increasing the effectiveness of the app and it can be used as
323 part of the therapeutic intervention or care method.

324 **Ethics approval:**

325 This paper is extracted from a master thesis. The Ethics Committee of Tehran University of
326 Medical Sciences (TUMS) (Ethical code= IR.TUMS.FNM. REC.1397.104) approved the study
327 protocol Informed written consent from the participant were obtain. This study was conducted in
328 accordance with the Declaration of Helsinki. All methods were performed in accordance with the
329 relevant guidelines and regulations in ethics approval and consent to participate.

330 **Limitations:**

331 One of the limitations of this study was the lack of access to an online interactive page for
332 interacting with users via the Internet, so instead, the WhatsApp social network was used as an
333 interactive environment. Another limitation of this study was that the researcher did not have
334 access to the interactive database and was unable to control the amount of application usage by
335 the user. For this purpose, telephone follow-up of users was used to ensure that the application
336 was being used. The application user also set goals for himself offline and recorded his calories

in the application. The researcher did not have the opportunity to ensure that reports were recorded in the application. To reduce this limitation, the application user was asked to take pictures of his lifestyle self-assessment, goal setting, calorie recording, and weight recording pages weekly and send them to the researcher via WhatsApp. The final criterion for the amount of weight loss was weight measurement using a standard scale in the gastroenterology clinic. To create motivation and competition between users to improve behavior, an interactive group was used on WhatsApp, where users could ask their questions and ambiguities and share their experiences. The names of the top performers in terms of weight loss per month in the interactive group were published.

Consent to participate:

Consent to participate: Written informed consent was obtained from all individual participants included in the study.

Consent for publication: Not Applicable. (This study does not contain any individual person's identifying images, videos, or clinical details that compromise anonymity).

Availability of data and materials:

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions. Protocol and statistical plan is available from the authors upon request.

Conflicts of interests:

The authors declare that they have no Conflicts of interests.

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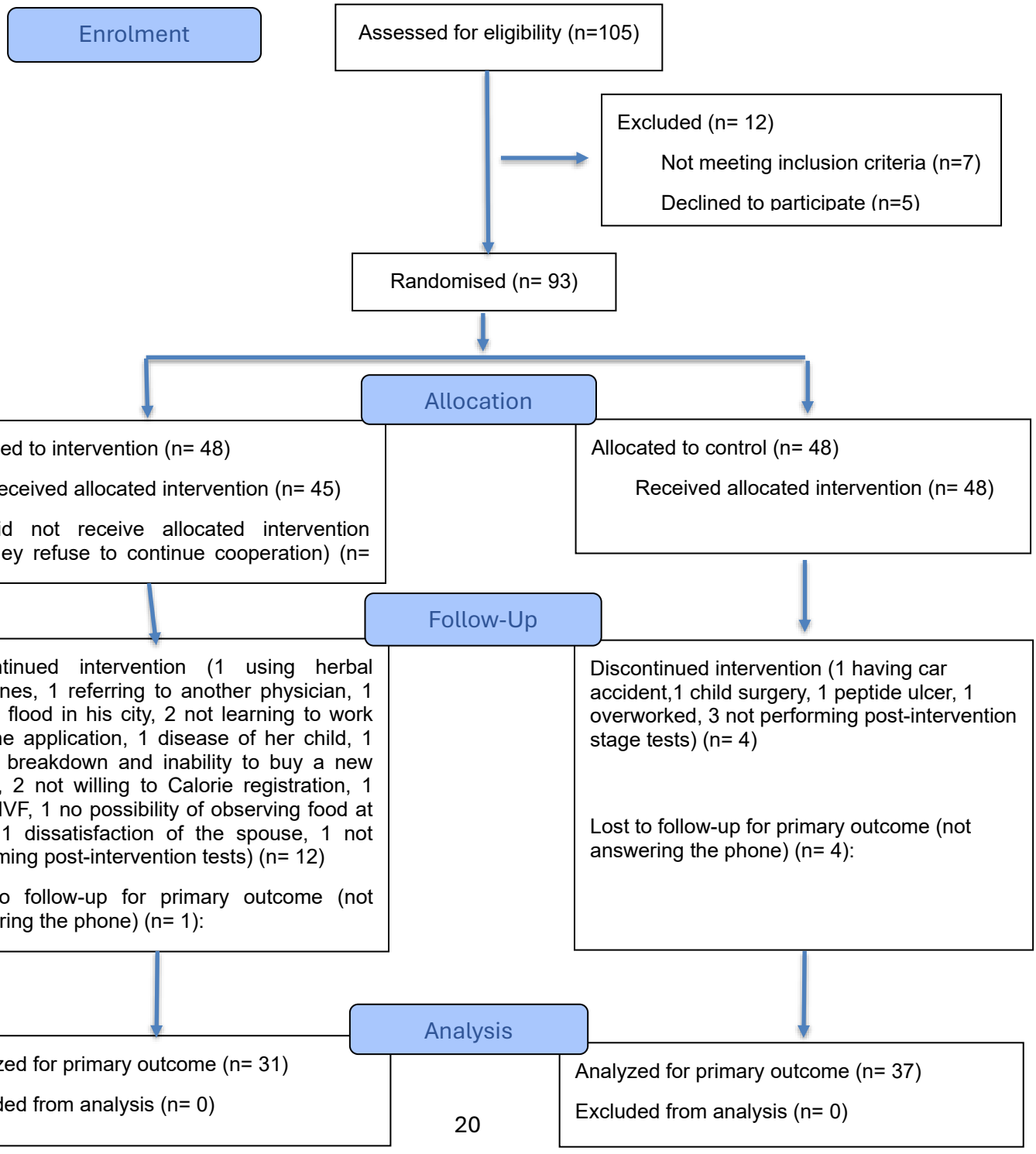
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Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram



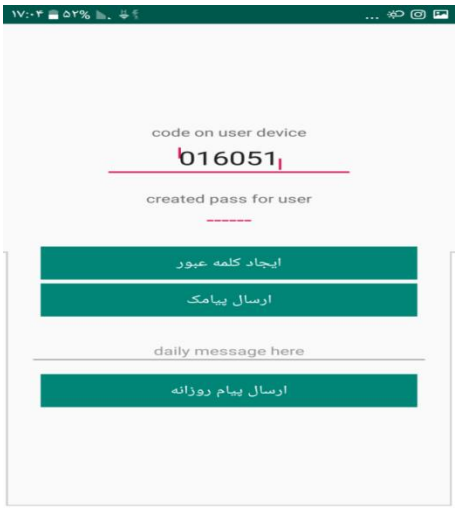


Figure 2: Create a unique password for each user

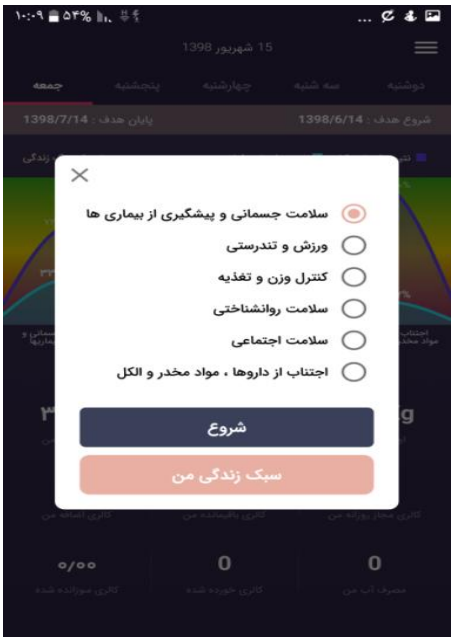


Figure 3: Lifestyle assessment form



Figure 4: User's lifestyle diagram



Figure 5: Self-care training text for user

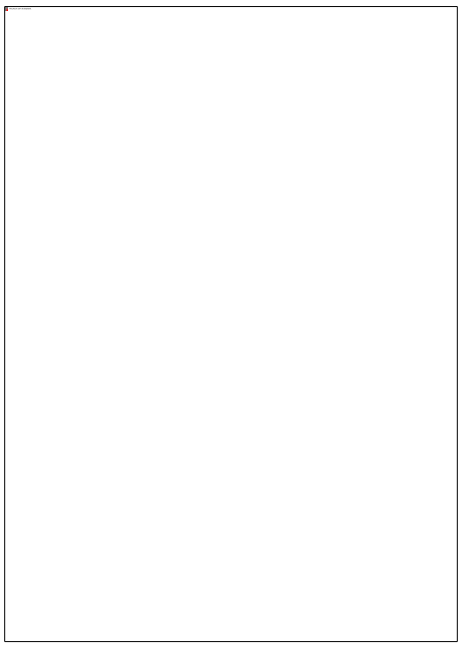


Figure 6: Calculation of the user's body mass index

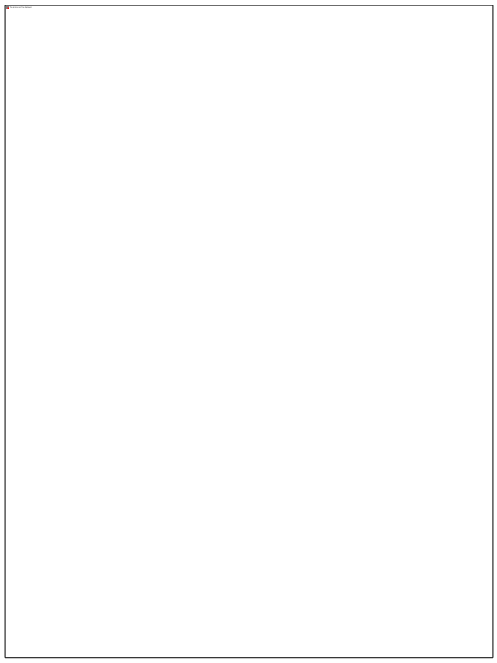


Figure 7: Targeting to reduce the user's weight

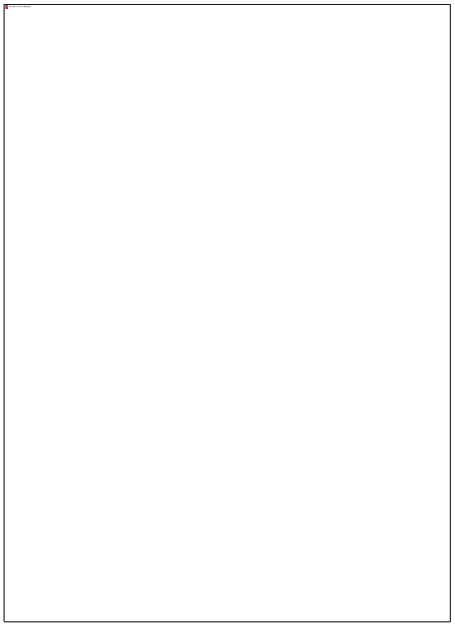


Figure 8. Separation of food by color for the user

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514 **Table 1: Lifestyles score for NAFLD patients in CG and EG before, one, two and three**
515 **months after intervention**

Lifestyle dimensions	Mean ± SD		P-value
	CG	EG	Independent t-test
Physical health and disease prevention (0-21)			
Before the intervention	12.04 (3.51)	11.36 (3.00)	0.399
One month after the intervention	15.05 (3.15)	15.41 (3.74)	0.668
Two months after the intervention	15.79 (2.67)	16.89 (2.44)	0.84
Three months after the intervention	16.88 (2.77)	17.98 (2.38)	0.84
Exercise and health (0-12)			
Before the intervention	5.86 (3.73)	6.61 (2.07)	0.215
One month after the intervention	7.64 (2.38)	8.51 (2.46)	0.146
Two months after the intervention	7.78 (2.46)	9.45 (2.18)	0.005
Three months after the intervention	8.32 (2.53)	10.09 (2.34)	0.004
Nutrition and weight control (0-21)			
Before the intervention	11.18 (4.26)	12.13 (3.90)	0.341
One month after the intervention	14.43 (4.17)	15.16 (3.35)	0.439
Two months after the intervention	15.13 (3.64)	17.32 (3.40)	0.006
Three months after the intervention	15.43 (3.86)	18.06 (3.41)	0.004
Psychological health (0-21)			
Before the intervention	12.6 (3.97)	14.98 (3.44)	0.01
One month after the intervention	13.19 (3.36)	16.24 (3.22)	0.011
Two months after the intervention	14.51 (3.75)	17.09 (3.71)	0.114
Three months after the intervention	14.79 (4.26)	18.09 (2.54)	0.01
Social health (0-9)			
Before the intervention	5.59 (1.65)	6.06 (1.76)	0.263
One month after the intervention	5.59 (1.65)	11.32 (1.01)	0.121
Two months after the intervention	6.18 (1.86)	7.29 (1.46)	0.263

Three months after the intervention	7 (1.76)	7.93 (1.26)	0.016
Avoidance of drugs and alcohol (0-12)			
Before the intervention	10.33 (2.00)	10.25 (2.40)	0.889
One month after the intervention	10.56 (2.06)	11.32 (1.01)	0.121
Two months after the intervention	10.97 (1.93)	11.54 (0.99)	0.21
Three months after the intervention	11.34 (1.75)	11.61 (1.05)	0.455
Total score (0-96)			
Before the intervention	57.67 (12.07)	61.46 (11.30)	0.189
One month after the intervention	66.51 (11.27)	73.27 (11.34)	0.017
Two months after the intervention	70.36 (10.51)	79.59 (10.24)	0.001
Three months after the intervention	73.77 (12.95)	83.79 (10.04)	0.001

Table 2: Comparing lifestyle of participants in the CG and EG before, 1, 2 and 3 months after the intervention

	Mean±SD of Life style				*Repeated measures ANOVA*
	Before	**1 months**	**2 months**	**3 months**	*(p-value)*
CG	57.67± 12.07	66.51±11.27	70.36±10.51	73.77±12.59	< 0.001
TG	61.46±11.30	73.27±11.34	79.59±10.34	83.79±10.04	< 0.001

Table 3: Laboratory indices before and after the intervention in the CG and EG (chi-square test)

	Laboratory indices		CG		TG		P-*value*
			Frequency	Percent	Frequency	Percent	
Before	Alanine aminotransferase	Normal	27	73	15	48.4	0.038
		Abnormal	10	27	15	51.6	
After	Cholesterol	Normal	27	73	30	96.8	0.008
		Abnormal	10	27	1	3.2	
	insulin	Normal	18	48.6	29	93.5	<0.001
		Abnormal	19	51.4	2	6.5	
	HOMA index	Normal	27	73	30	96.8	0.008
		Abnormal	10	27	1	3.2	

Table 4: Comparing liver laboratory indicators of patients of CG and TG before and three months after the intervention

Laboratory indices				After				Mc Nemar' test
				Abnormal		Normal		(p-value)
				Frequency	Percent	Frequency	Percent	0.013
Control Group/ Before		FBS	Abnormal	5	13.5	12	32.4	
			Normal	2	5.4	18	48.6	
		ALT	Abnormal	2	5.6	7	19.4	0.016
			Normal	0	0.00	27	75	
		TG	Abnormal	6	19.4	8	25.8	0.008
			Normal	0	0. 0	17	54.8	
		Chol	Abnormal	1	3.2	10	32.3	0.002
			Normal	0	00.0	20	64.5	
Experimental group/ Before		HDL	Abnormal	1	3.2	2	6.5	0.001
			Normal	3	9.7	25	80.6	
		LDL	Abnormal	8	25.8	14	45.2	0.004
			Normal	2	25.8	7	22.6	
		Insulin	Abnormal	2	6.5	8	25.8	0.008
			Normal	0	0.00	21	67.7	
		AST	Abnormal	1	3.2	8	25.8	0.039
			Normal	1	3.2	21	67.7	
		ALT	Abnormal	1	3.2	15	48.4	0.002
			Normal	2	6.5	13	41.9	

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Supplementary Files

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