Session III

Technology-based interventions

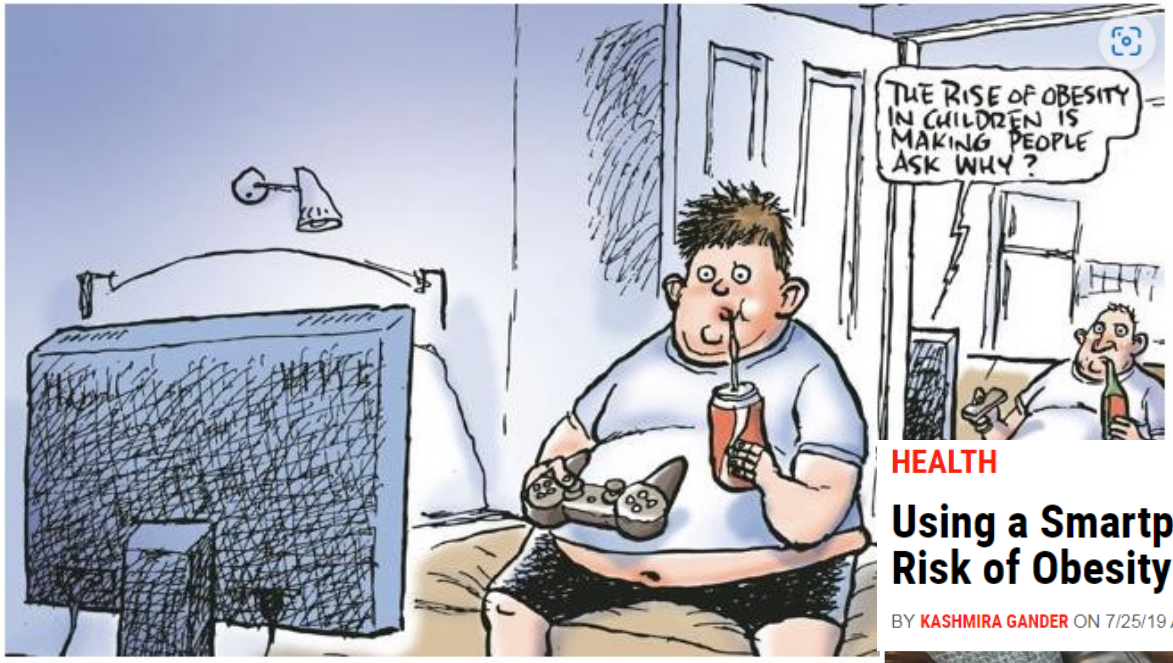
Digital Therapeutics for Obesity

서 유 빈

원광대 산본병원

Contents

IBesity



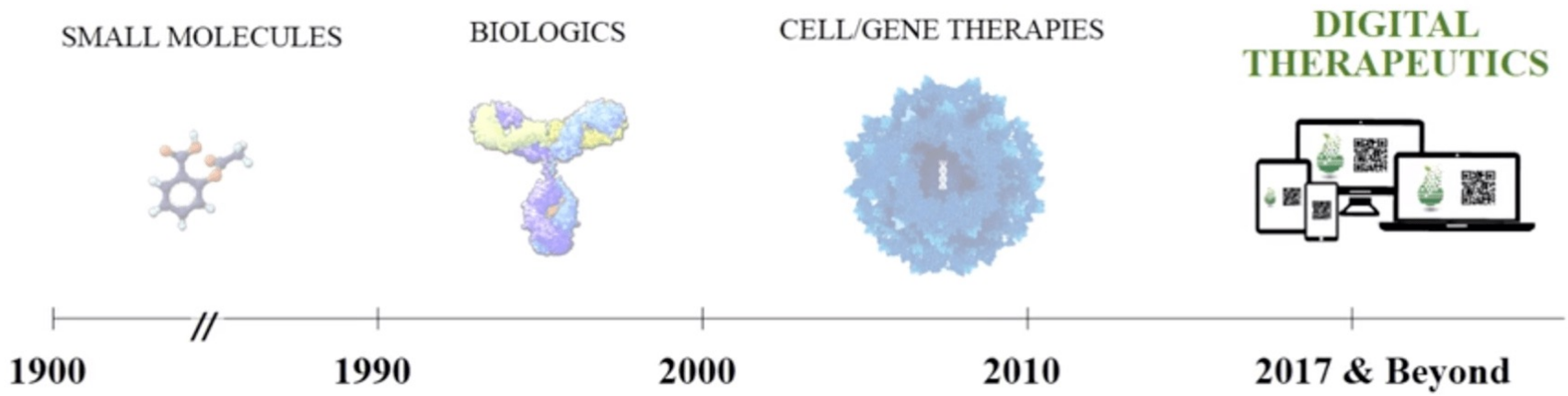
HEALTH

Using a Smartphone for This Long Could Raise the Risk of Obesity

BY KASHMIRA GANDER ON 7/25/19 AT 2:45 PM EDT

medium.com/@mebrin/ibesity-713346b714ec

www.newsweek.com/using-smartphone-this-long-could-raise-risk-obesity-1451104



Canadian Adult Obesity Clinical Practice GUIDELINES

Emerging Technologies and Virtual Medicine in Obesity Management

obesity canada | obésité canada

L'ASSOCIATION CANADIENNE des MÉDECINS et CHIRURGIENS BARIATRIQUE
The CANADIAN ASSOCIATION of BARIATRIC PHYSICIANS and SURGEONS

RECOMMENDATIONS

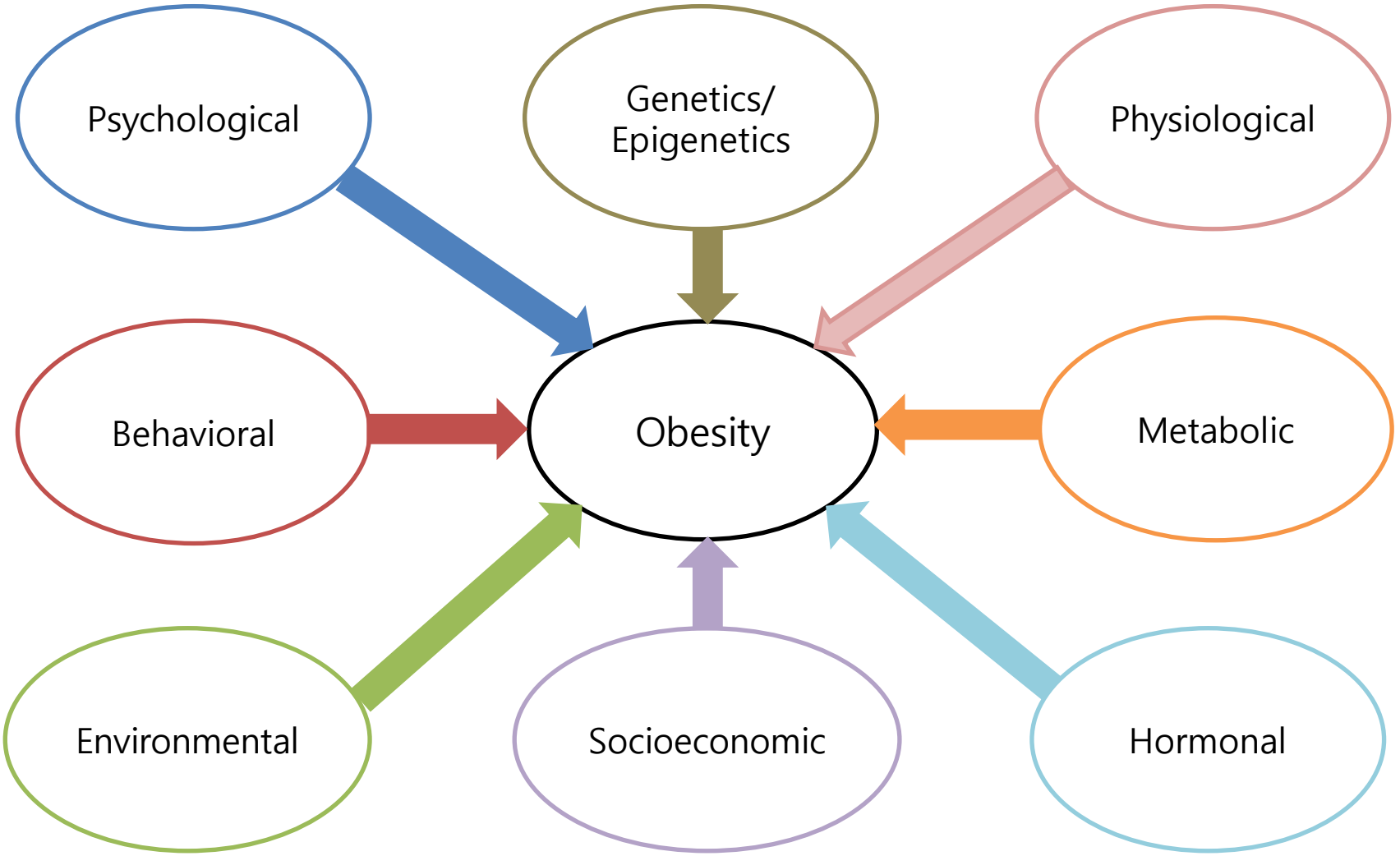
1. Implementation of management strategies can be delivered through web-based platforms (e.g., online education on medical nutrition therapy and physical activity) or mobile devices (e.g., daily weight reporting through a smartphone phone application) in the management of obesity (Level 2a, Grade B).[1,2]

2. We suggest that healthcare providers incorporate individualized feedback and follow-up (e.g., personalized coaching or feedback via phone or email) into technology-based management strategies to improve weight loss outcomes (Level 4, Grade D).[3]

3. The use of wearable activity tracking technology should be used as part of a comprehensive strategy for weight loss (Level 1a, Grade A).[4]

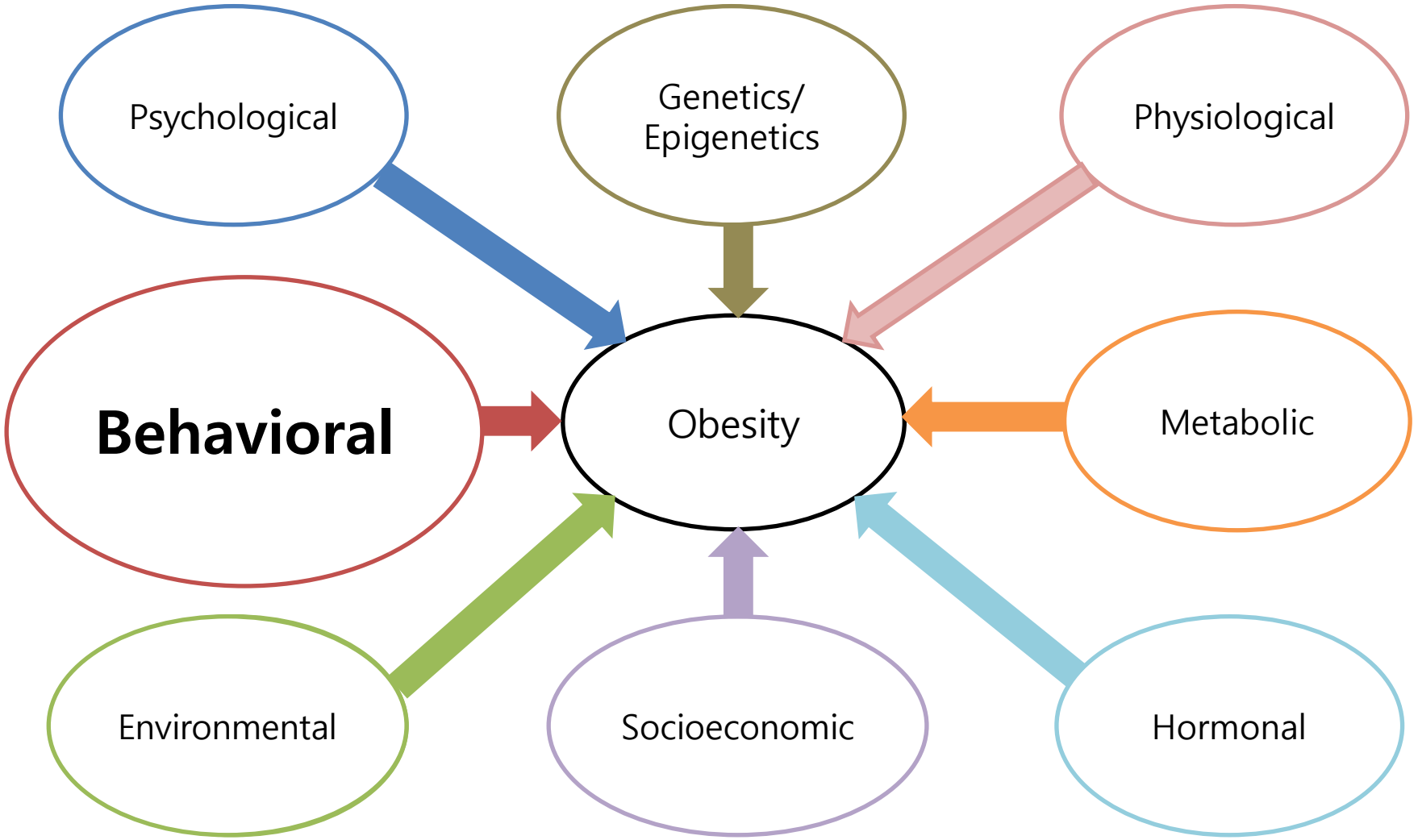
https://obesitycanada.ca/guidelines/technologies/

Multifactorial etiology of obesity



Pharmacoeconomics. 2015 Jul;33(7):673-89

Multifactorial etiology of obesity



Pharmacoeconomics. 2015 Jul;33(7):673-89

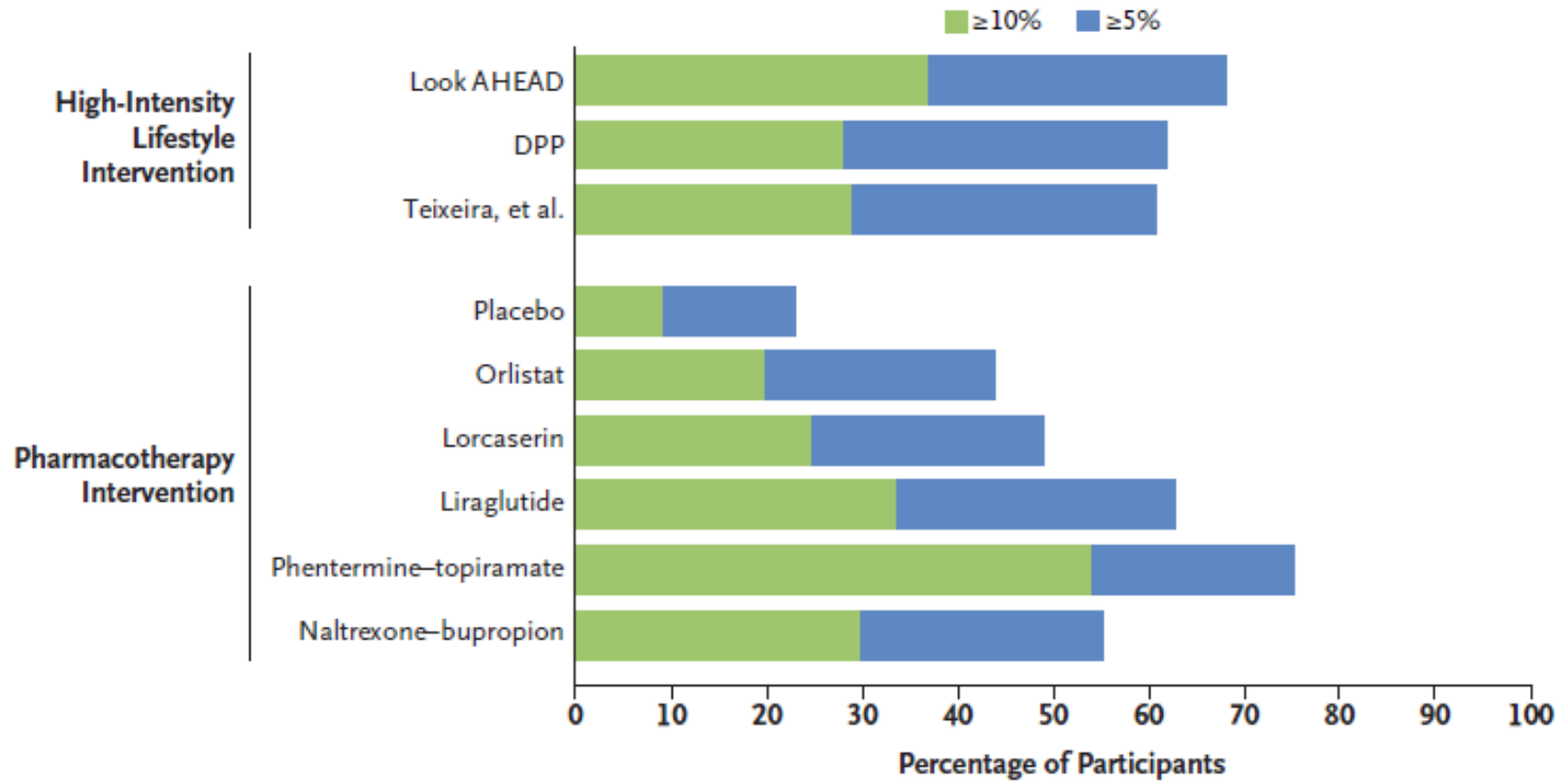


Figure 2. Weight Loss at 1 Year with High-Intensity Lifestyle Interventions or Pharmacotherapy Combined with Low-to-Moderate-Intensity Lifestyle Counseling.

Original Article
CLINICAL TRIALS: BEHAVIOR, PHARMACOTHERAPY, DEVICES, SURGERY

Eight-Year Weight Losses with an Intensive Lifestyle Intervention: The Look AHEAD Study

The Look AHEAD Research Group

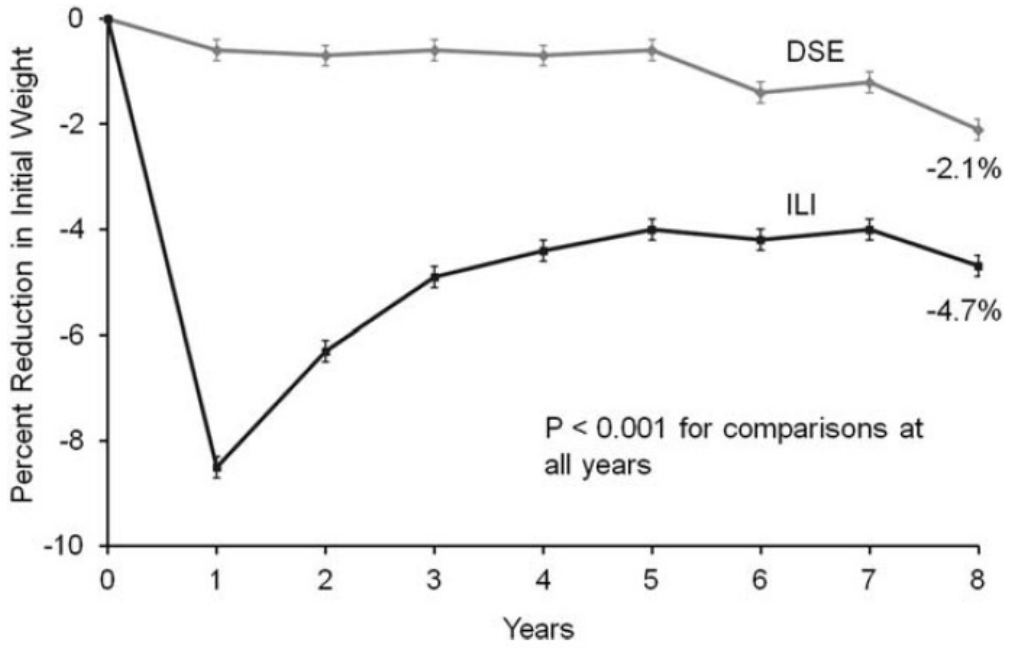


Figure 2 Figure shows mean (±SE) weight losses over 8 years for participants randomly assigned to an intensive lifestyle intervention (ILI) or diabetes support and education (DSE; usual care group). Differences between groups were significant ($P < 0.001$) at all years.

→ Look AHEAD's intensive lifestyle intervention produced clinically meaningful weight loss (5%) at year 8 in 50% of patients with type 2 diabetes and can be used to manage other obesity-related co-morbid conditions.

Obesity (Silver Spring) 2006;14:737-752.

REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP*

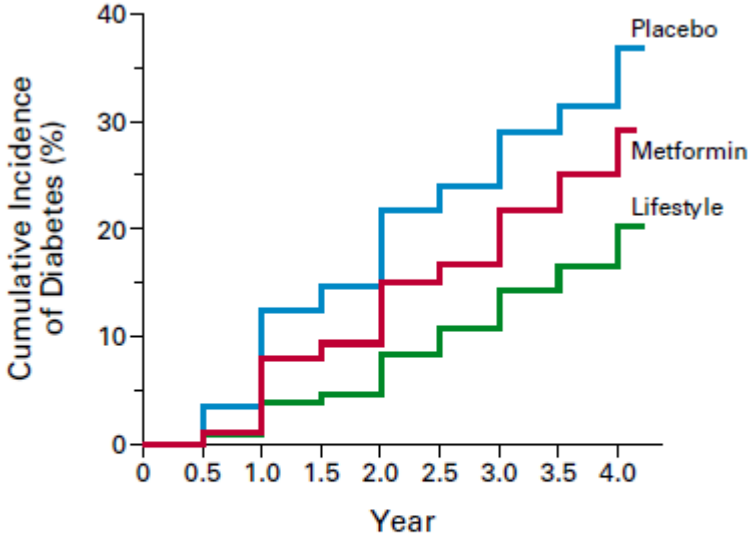


Figure 2. Cumulative Incidence of Diabetes According to Study Group.

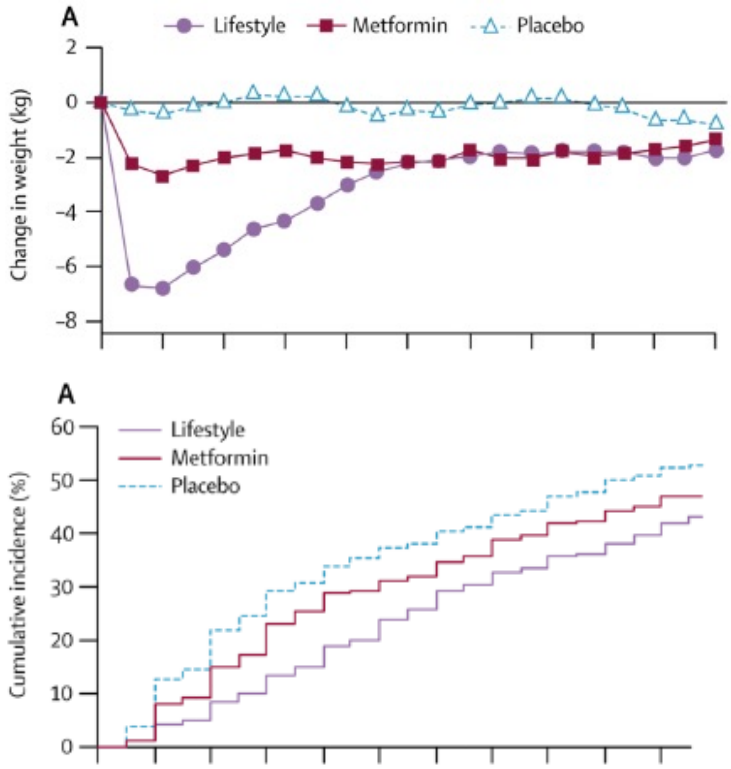
The diagnosis of diabetes was based on the criteria of the American Diabetes Association.[11] The incidence of diabetes differed significantly among the three groups ($P<0.001$ for each comparison).

→ Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.

N Engl J Med 2002;346:393-403.

10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study

Diabetes Prevention Program Research Group*



→ Prevention or delay of diabetes with lifestyle intervention or metformin can persist for at least 10 years.

Lancet. 2009 November 14; 374(9702): 1677–1686.

ICT

Figure 4. Lifestyle Therapy

Evidence-based lifestyle therapy for treatment of obesity should include 3 components
Recommendations: R64 through R75

Meal Plan (R64, R65, R66)

- Reduced-calorie healthy meal plan
- ~500–750 kcal daily deficit
- Individualize based on personal and cultural preferences
- Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian
- Meal replacements
- Very low-calorie diet is an option in selected patients and requires medical supervision

Team member or expertise: dietitian, health educator

Physical Activity (R64, R67, R68, R69, R70, R71)

- Voluntary aerobic physical activity progressing to >150 minutes/week performed on 3–5 separate days per week
- Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week
- Reduce sedentary behavior
- Individualize program based on preferences and take into account physical limitations

Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist

Behavior (R64, R72, R73, R74, R75)

An interventional package that includes any number of the following:

- Self-monitoring (food intake, exercise, weight)
- Goal setting
- Education (face-to-face meetings, group sessions, remote technologies)
- Problem-solving strategies
- Stimulus control
- Behavioral contracting
- Stress reduction
- Psychological evaluation, counseling, and treatment when needed
- Cognitive restructuring
- Motivational interviewing
- Mobilization of social support structures

Team member or expertise: health educator, behaviorist, clinical psychologist, psychiatrist

AACE/ACE Guidelines, 2016

Digital delivery of behavioral intervention

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

National Diabetes Prevention Program

Español (Spanish) | Print

About the National Diabetes Prevention Program

Congress authorized CDC to establish the **National Diabetes Prevention Program (National DPP)**, a public-private partnership working to build a nationwide delivery system for a lifestyle change program **proven to prevent or delay type 2 diabetes** in adults with prediabetes.

Lifestyle Change Program

A key part of the National DPP is a **lifestyle change program** that provides:

- **A trained lifestyle coach**
- **CDC-approved curriculum**
- **Group support over the course of a year**

omada

noom

PRESS RELEASE

Omada Health Achieves Full CDC Recognition

Digital Therapeutics Pioneer Becomes Largest Diabetes Prevention Program Provider to Achieve Milestone

San Francisco, CA (May 30, 2018) -- Omada Health today announced that the company has graduated to full recognition status from the Centers for Disease Control and Prevention (CDC). Omada now becomes the largest Diabetes Prevention Program (DPP) provider, in-person or virtual, to achieve full recognition from the CDC.

BMJ Open Diabetes Research & Care

Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update

Omada Health Program

accessible via **internet-enabled desktop or mobile devices**

- one year of a behavior change curriculum approved by the CDC DPRP
- 16-week DPP-based weight loss intervention - ongoing weight maintenance intervention
- **technology-enabled tools** to track nutritional intake, physical activity and body weight
- weekly lessons, personalized health coaching, online social network

- Single-arm, nonrandomized trial, 220 prediabetes patients: baseline mean Wt 100.2kg, BMI 36.4, A1c 5.98

Table 2B Changes from baseline in body weight and A1c for participants who completed nine or more lessons (n = 155)

	Weight change (lb)		Weight change (%)		A1c change	
Time point	Mean (SE)*	p Value	Mean (SE)*	p Value	Mean (SE)*	p Value
16 weeks	−11.6 (0.7)	<0.0001	−5.2 (0.3)	<0.0001	+0.03 (.06)	0.62
1 year	−10.2 (0.9)	<0.0001	−4.9 (0.5)	<0.0001	−0.40 (.07)	<0.0001
2 years	−8.3 (1.4)	<0.0001	−4.3 (0.8)	<0.0001	−0.46 (.08)	<0.0001
3 years	−6.3 (2.1)	0.0024	−2.9 (1.0)	0.0024	−0.33 (.09)	0.0005

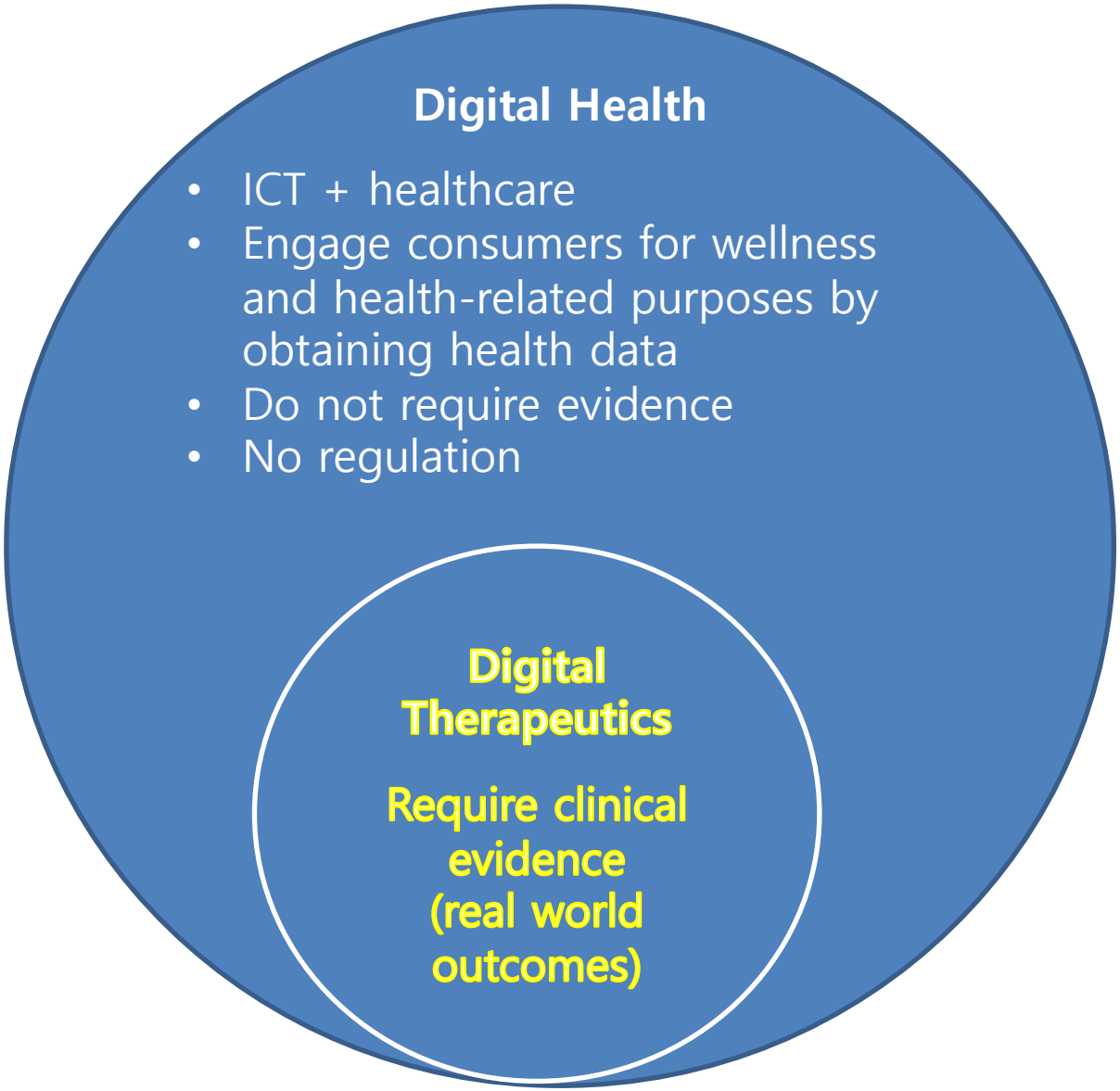
Overview of technology-based interventions

Health care and ICT (Information & Communications Technology)

표 1 헬스케어와 ICT 융합을 통한 보건·의료 서비스의 발전과정[14)15)16)]

구분	Telehealth	e-Health	u-Health (Ubiquitous Health)	s-Healthcare (Smart healthcare)	Digital Healthcare (s-healthcare + Mobile-health)
시기	1990년 중반 ~	2000년 ~	2000년 중반 ~	2010년 ~	2015년 이후 ~
정보화 수준	병원정보화	병원 간 정보교류	- 병원 간 정보교류 - 병원-환자 간 정보교류	의료, 복지, 건강 관리 등 종합 정보화	
기반 ICT 기술	네트워킹	초고속 인터넷	무선 인터넷	- 스마트기기 - 앱스토어	- 웨어러블/모바일 기기 - VR/AR
주요 서비스 시스템	병원 운영 - HIS* - OCS* - PACS*	의무기록(EMR)* 웹사이트	건강기록(EHR)* 모니터링	개인건강기록(PHR)* 및 사례기반추론(CBR)* 기반 맞춤형 서비스	- IoT 기반 PHR - 클라우드 - 빅데이터 - 인공지능 - 디지털 치료제
서비스 내용	원내 치료	- 치료 - 정보제공	- 치료 - 정보제공 - 예방	- 치료 - 예방 - 복지 - 안전	
주요 공급자/ Player	병원	병원	- 병원 - ICT 기업	병원, ICT 기업, 제약회사, 스포츠 기업, 보험사, 서비스 기업 등 다양화	
주요 수요자/ 이용자	의료인	- 의료인 - 환자	- 의료인 - 환자 - 일반인	의료인, 환자, 일반인, 기업, 정부 등 다양화	

Electronics and Telecommunications Research institute, 2020



J Med Internet Res 2005;7:e9.

Fam Med Prim Care Rev, 9(5), 2207.

Definition

Digital therapeutics (DTx)

DTx deliver to patients **evidence-based** therapeutic interventions
that are driven by high quality **software** programs
to **treat, manage, or prevent** a disease or disorder.

They are used **independently** or in concert **with** medications, devices, or other therapies to optimize patient care and health outcomes.

Digital therapeutics alliance
https://dtxalliance.org/understanding-dtx/what-is-a-dtx/

Major DTx products and companies.

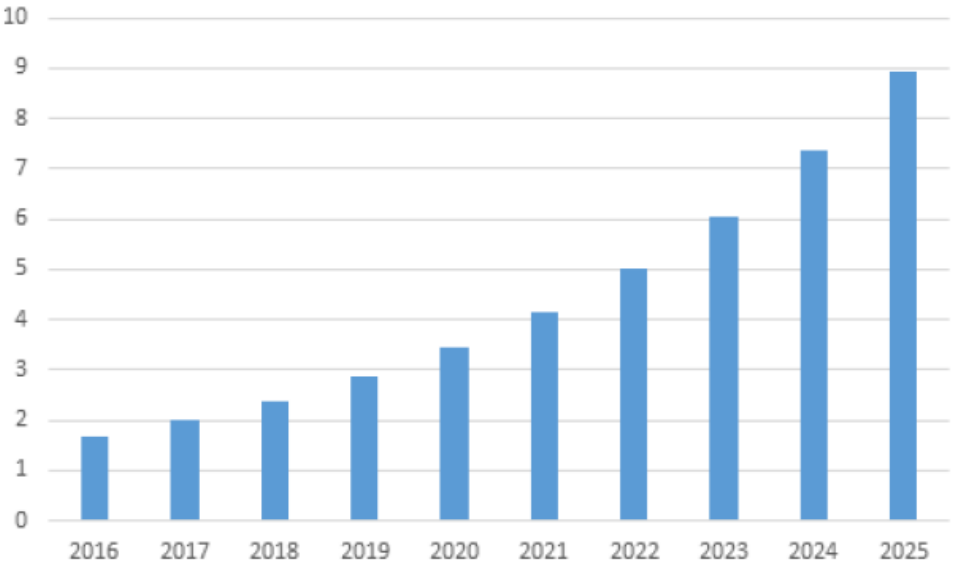
Classification	Product	Company	Device classification	Therapeutic area	Approval status	Partnership
Prescription DTx	BlueStar [24–28]	WellDoc	Mobile app/web portal connected to blood glucose meter - infusion pump accessories (MRZ); Medical computers and software (LNX)	Type 1 and type 2 diabetes	FDA-510(k)	Lifescan; Voluntis; Samsung
	Insulia [29,30]	Voluntis	Mobile app/web portal - drug dose calculator (NDC)	Type 2 diabetes	FDA-510(k) EU-CE Mark	Sanofi; Livongo; Onduo; Verily; Monarch
	reset [31]	Pear Therapeutics	Mobile app - computerized behavioral therapy device for psychiatric disorders (PWE)	Substance use disorder (SUD)	FDA-de novo	Novartis' Sandoz
	reSET-O [31,32]	Pear Therapeutics	Mobile app - computerized behavioral therapy device for psychiatric disorders (PWE)	Opioid use disorder (OUD)	FDA-510(k)	Novartis' Sandoz
	Freespira [33–35]	Palo Alto Health Sciences	Mobile app - biofeedback device (HCC); Carbon dioxide gas analyzer (CCK)	Panic disorder and post-traumatic stress disorder	FDA-510(k)	Silicon Valley TMS
	Natural Cycles [36,37]				ıovo	-
	Propeller Health [38,39]				(k) EU-CE	Novartis; Boehringer Ingelheim; GSK
	ProAir Digihaler [40]		management - digital inhaler with built-in sensors that connects to a companion mobile app		(k)	-
	EndeavorRx (ALK-T01) [21]	Akili	Video game	Pediatric ADHD	FDA-510(k) EU-CE Mark	
	Somryst [41]	Pear therapeutics	Mobile app - cognitive behavioral therapy for insomnia (CBTi) and sleep restriction	Chronic insomnia	FDA-510(k)	-
	Oleena [42]	Voluntis	Mobile app/web portal - oncology-related symptoms management and remote patient monitoring	All cancer	FDA-510(k)	-
	Kaia Back Pain Relief [43]	Kaia	Mobile app	Chronic, nonspecific low back pain	-	Min Doktor
	Sleepio [44–46]	Big Health	Mobile app - computerized behavioral therapy device for psychiatric disorders (PWE)	Sleep disorders	NICE	CVS Health
Non-Prescription DTx	Diabeo [47–49]	Voluntis	Mobile app/web portal	Type 1 and type 2 diabetes	EU-CE Mark	Sanofi; Onduo; Verily
	Daylight [44,50]	Big Health	Mobile app - computerized behavioral therapy device for psychiatric disorders (PWE)	Worry and anxiety	-	CVS Health
	Clickotine [51,52]	Click Therapeutics	Mobile app	Smoking cessation	-	Megellan Health; Sanofi; Otsuka
	CureApp-SC [53,54]	CureApp, Inc.	Mobile app; portable CO checker	Smoking cessation	MHLW (Japan)	-
	Kaia App COPD Therapy	Kaia	Mobile app	COPD	-	-

Behavioral therapy
Chronic disease management
Patient data collection and analysis

Comput Methods Programs Biomed. 2021;209:106319

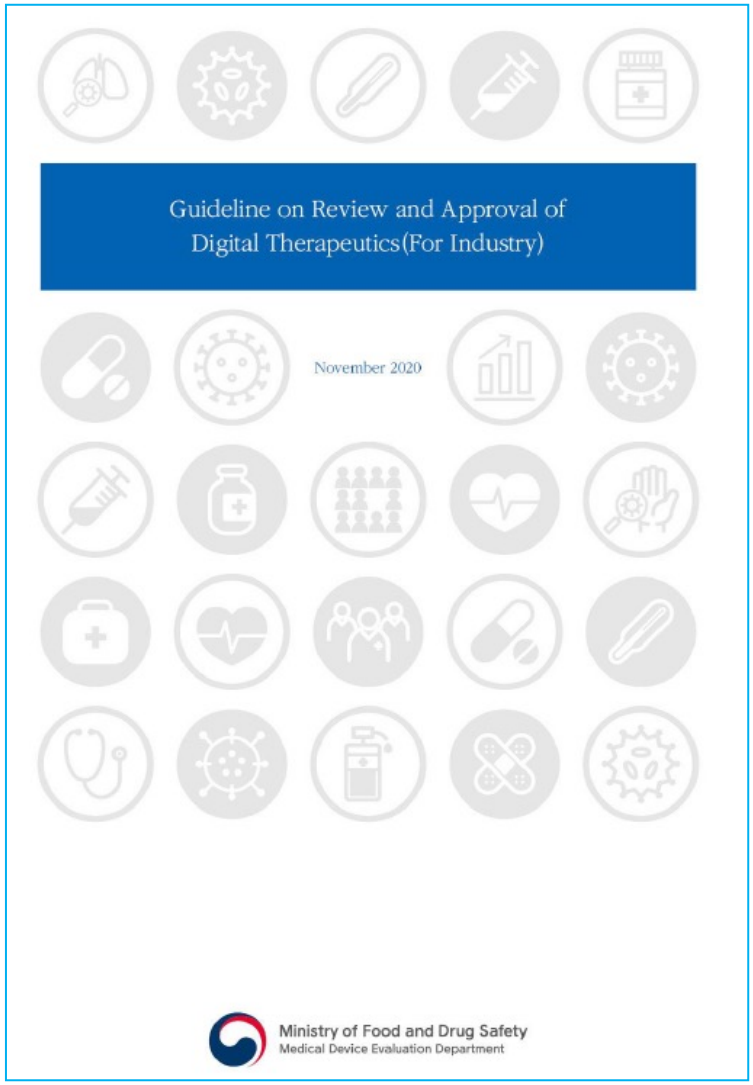
[그림 5] 디지털 치료제 관련 미국 특허출원 수

[그림 6] 디지털 치료제 관련 FDA 임상시험 건수 (ClinicalTrial.gov)



[그림 10] 2016-2025년 전세계 디지털 치료제 시장 규모(단위: 십억 불)

KISTEP 한국과학기술기획평가원 Korea Institute of S&T Evaluation and Planning



디지털 치료기기 확증임상 승인 현황

의뢰회사	승인일	제품명	제품 설명
뉴냅스	2019년 6월13일	뉴냅비전	뇌손상 시야장애 개선
라이프시맨틱스	2021년 9월3일	레드필 숨튼	호흡 재활
에임메드	2021년 9월10일	솜즈	불면증 치료
웰트	2021년 9월27일	필로우Rx	불면증 치료
하이	2021년 12월30일	엥자이렉스	범불안장애 치료
웰트	2022년 5월30일	필로우Rx (DCT 솔루션 적용)	불면증 치료
뉴냅스	2022년 8월1일	비비드 브레인	뇌질환 시야장애 개선
이모코그	2022년 9월28일	코그테라	경도인지장애 치료
메디마인드	2022년 10월20일	알코테라	알코올 사용장애 개선
A	2022년 10월28일	SMD SleepDoc	비기질성 불면장애 개선

https://news.mt.co.kr/mtview.php?no=2022111109221021866

- Approval / Certification of manufacturing / Import
- Evaluation of technical documents
- Approval of clinical trial plans for DTx

Examples of interventions using technologies

- Web-based intervention
- Mobile application
- Wearable devices
- Virtual reality / Augmented reality
- Artificial intelligence



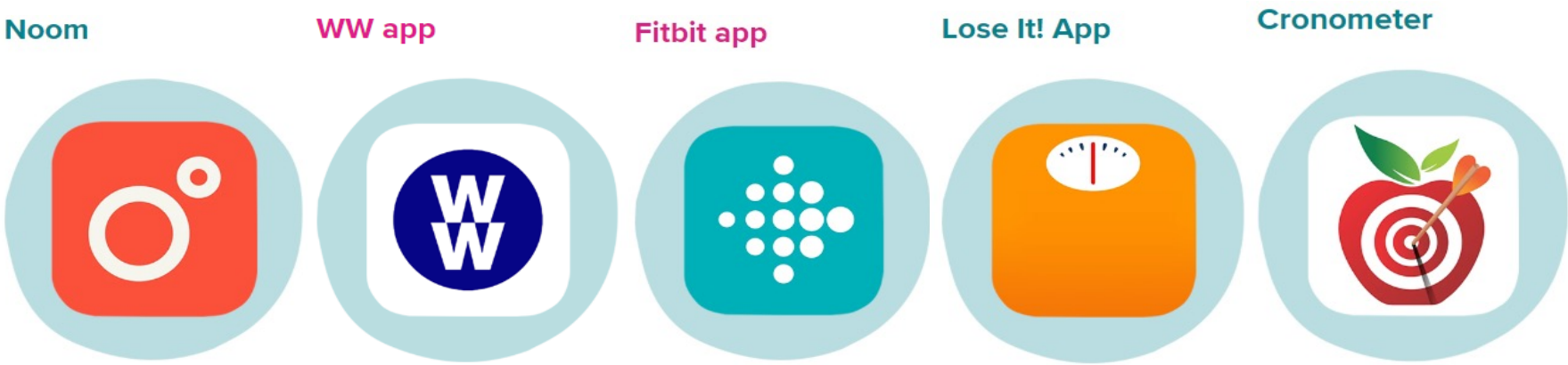



Mobile application

- Support behavioral change by more interactive and timely access to information and delivering assistance

Common features

- Food and exercise logging
- Body weight monitoring

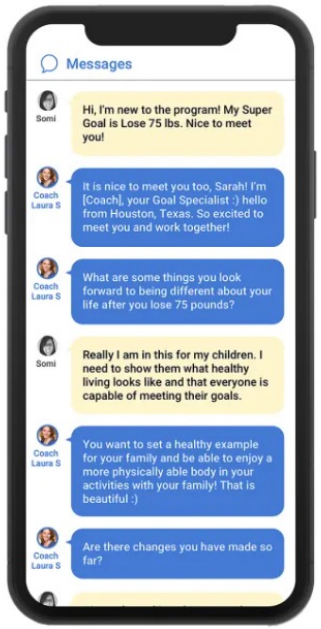


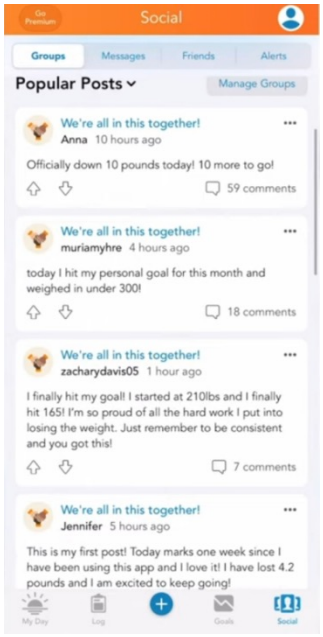
JMIR mhealth uhealth. 2020;8(7):e17039

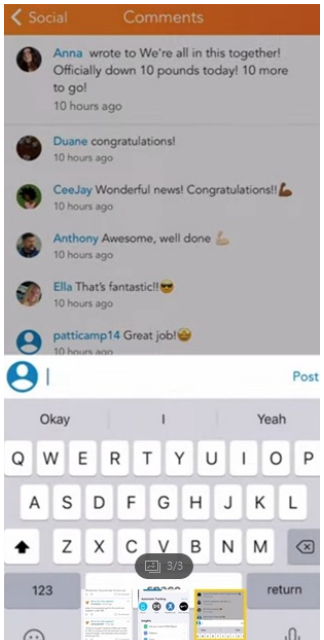
Mobile application

Extra features

- Barcode scanners
- Provide feedback
- Support forums (social networking)
- Sync with other health and fitness apps or devices



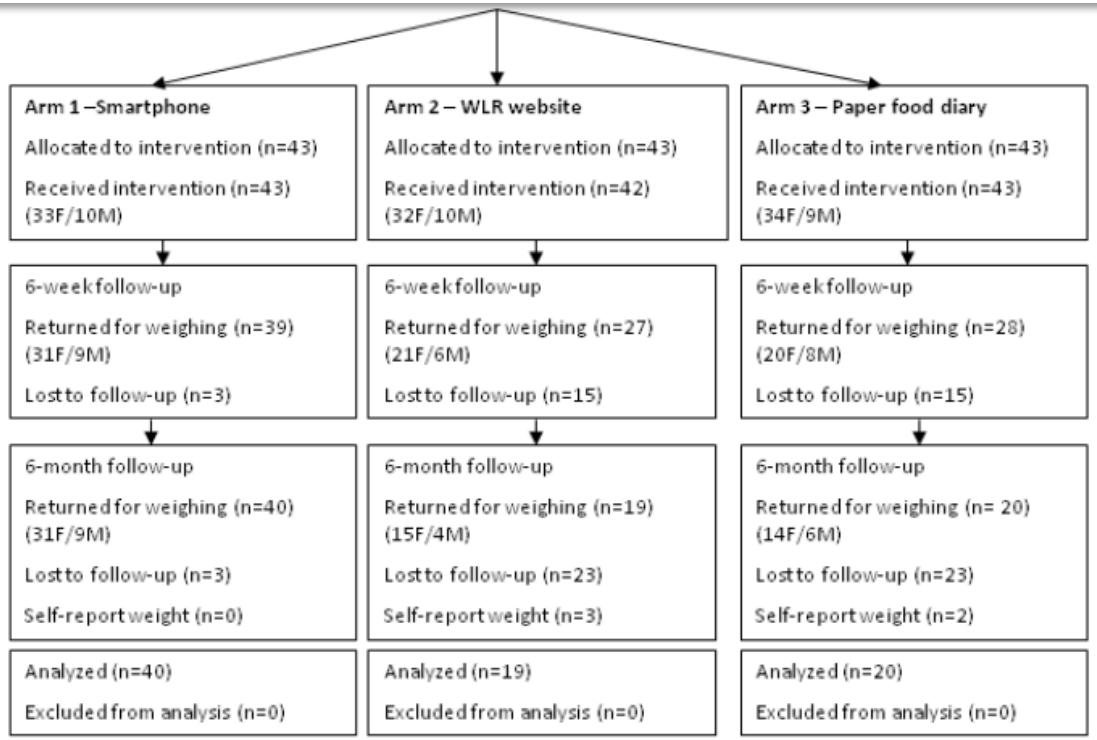




Original Paper

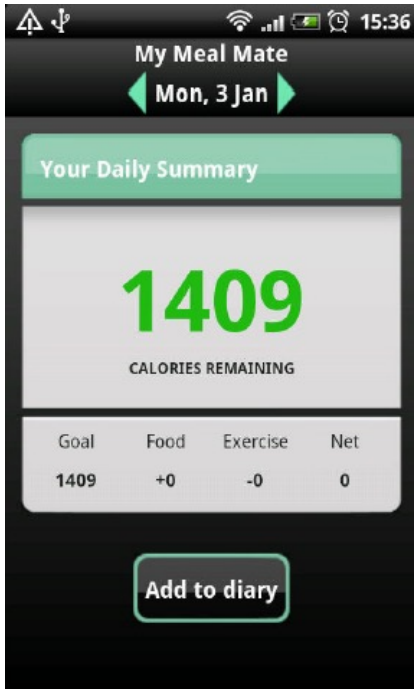
Adherence to a Smartphone Application for Weight Loss Compared to Website and Paper Diary: Pilot Randomized Controlled Trial

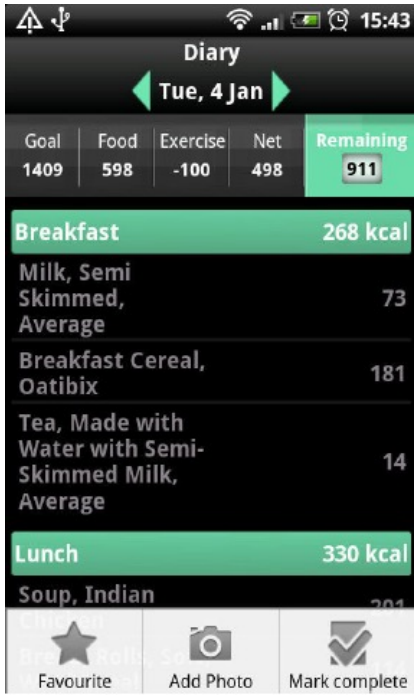
Michelle Clare Carter, MA, RD; Victoria Jane Burley, MSc, PhD; Camilla Nykjaer, MSc; Janet Elizabeth Cade, MSc, PhD



Three-armed RCT
128 overweight volunteers
Weight change at 6 months

J Med Internet Res. 2013;15(4):e2283





Smartphone app: My Meal Mate

Goal setting
Self-monitoring of diet and activity
Feedback via weekly text message

Website: Weight Loss Resources

Similar self-monitoring intervention to the app

Trial retention
Smartphone 93% / website group 55% / diary 53%
Adherence
Smartphone 92 days / website group 35 days / diary 29 days

Table 5. Change in anthropometric measures using an intention-to-treat[a] analysis.

Anthropometric measurements	Smartphone		Diary		Website		P[b]
	n	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)	
Weight (kg)							
Baseline	43	96.8 (91.9-101.8)	43	97.9 (92.2-103.6)	42	96.4 (90.2-102.6)	
6 weeks	43	93.9[c] (89.0-99.0)	43	95.9[c] (89.8-101.7)	42	95.1[c] (89.0-101.2)	.001
6 months	43	92.2[c] (87.0-97.4)	43	95.0[c] (89.0-101.0)	42	95.1 (89.0-101.3)	<.001
BMI (kg/m^2)							
Baseline	43	33.7 (32.4-35.0)	43	34.5 (32.7-36.2)	42	34.5 (32.7-36.2)	
6 weeks	43	32.6[c] (31.3-33.9)	43	33.7[c] (31.9-35.5)	42	34.0 (32.3-35.7)	<.001
6 months	43	32.1[c] (30.7-33.5)	43	33.4 (31.5-35.4)	42	34.0 (32.3-35.8)	<.001
Body fat (%)							
Baseline	42	35.9 (34.7-37.1)	42	36.0 (34.5-37.5)	42	36.3 (35.1-37.5)	
6 weeks	42	35.0[c] (33.7-36.2)	42	35.3[c] (33.8-36.9)	42	36.0 (34.7-37.2)	.01
6 months	42	34.7[c] (33.5-35.9)	42	35.1 (33.4-36.7)	42	35.9 (34.5-37.2)	.02

6 months: -4.6 kg vs -2.9 kg vs -1.3 kg

J Med Internet Res. 2013;15(4):e2283

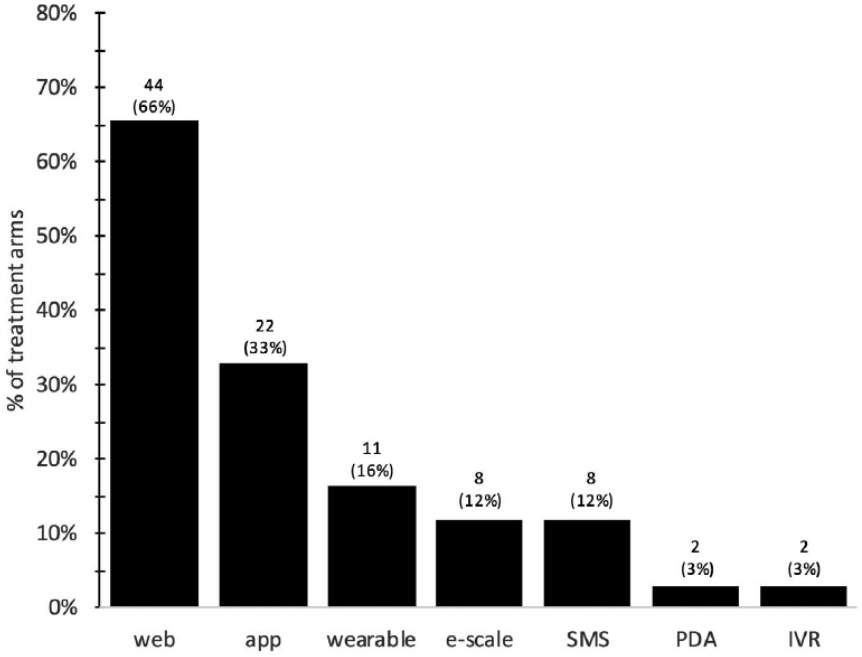
Review
CLINICAL TRIALS AND INVESTIGATIONS

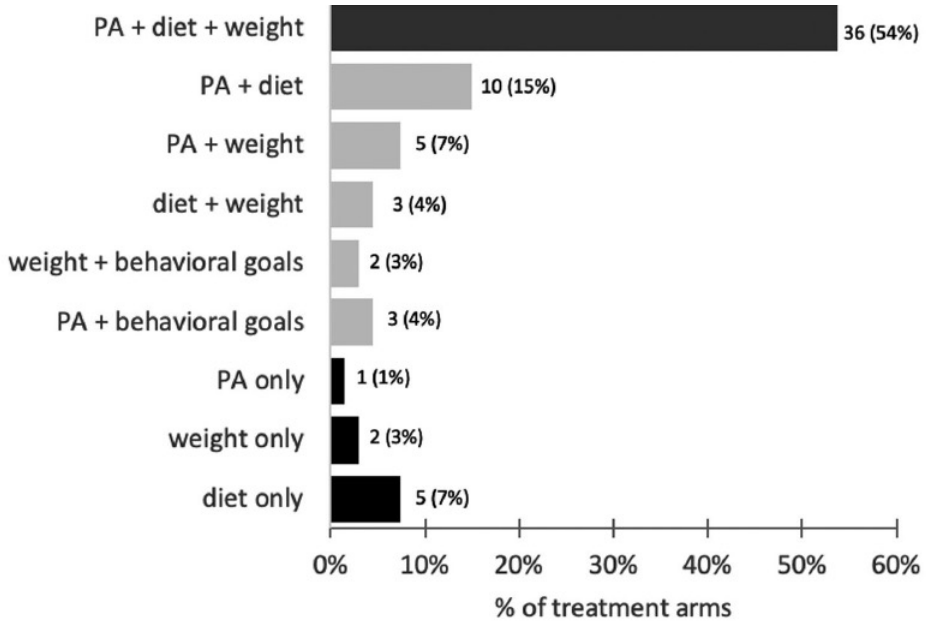
Obesity

Self-Monitoring via Digital Health in Weight Loss Interventions: A Systematic Review Among Adults with Overweight or Obesity

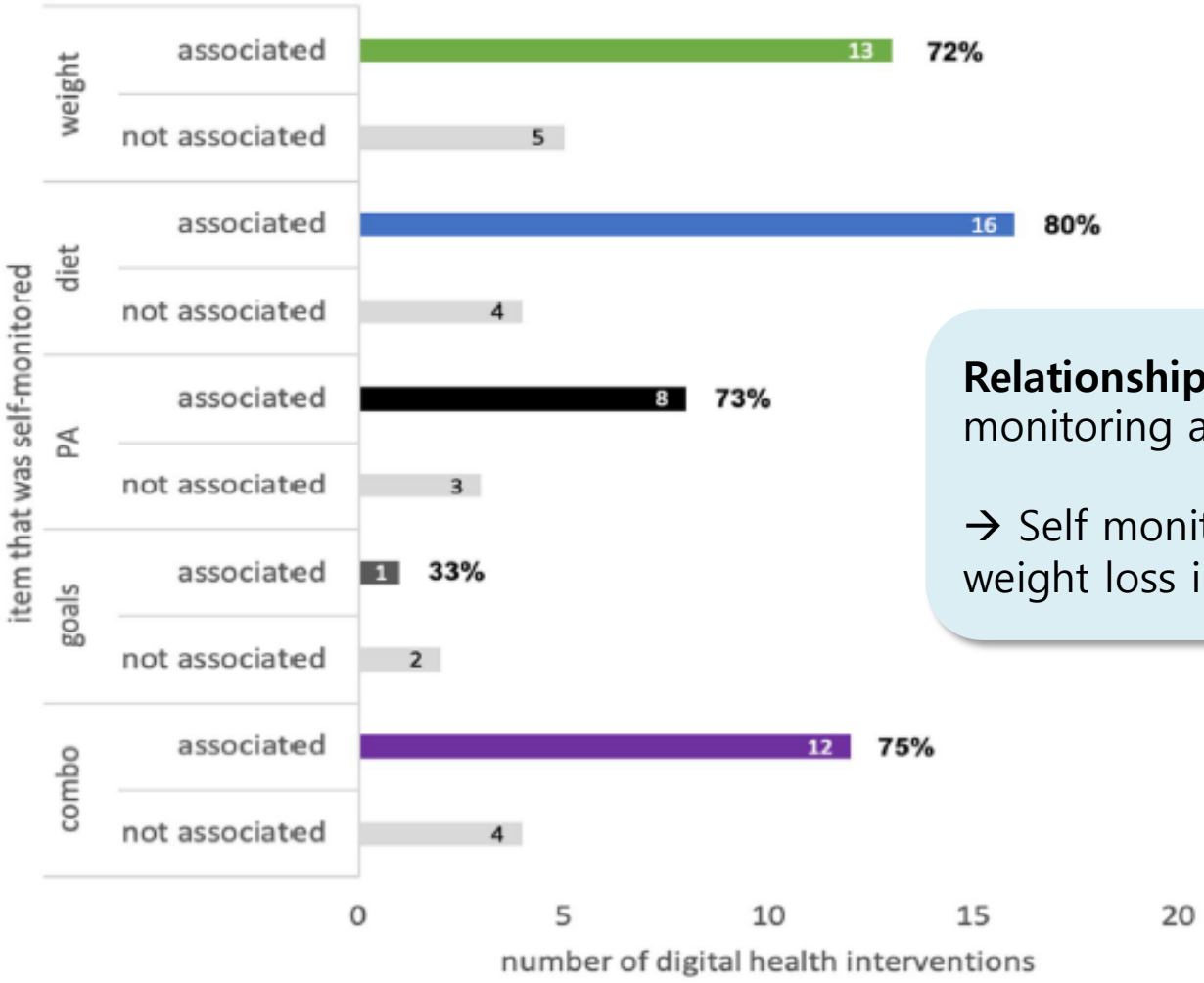
Michele L. Patel [1], *Lindsay N. Wakayama*[2], *and Gary G. Bennett* [3,4]

Systematic review of 39 RCTs, (67 interventions)
-Interventions ≥ 12 weeks
-Weight outcomes ≥ 6 months





Obesity, 2021:29(3): 478-499.



Relationship between digital self-monitoring and weight loss

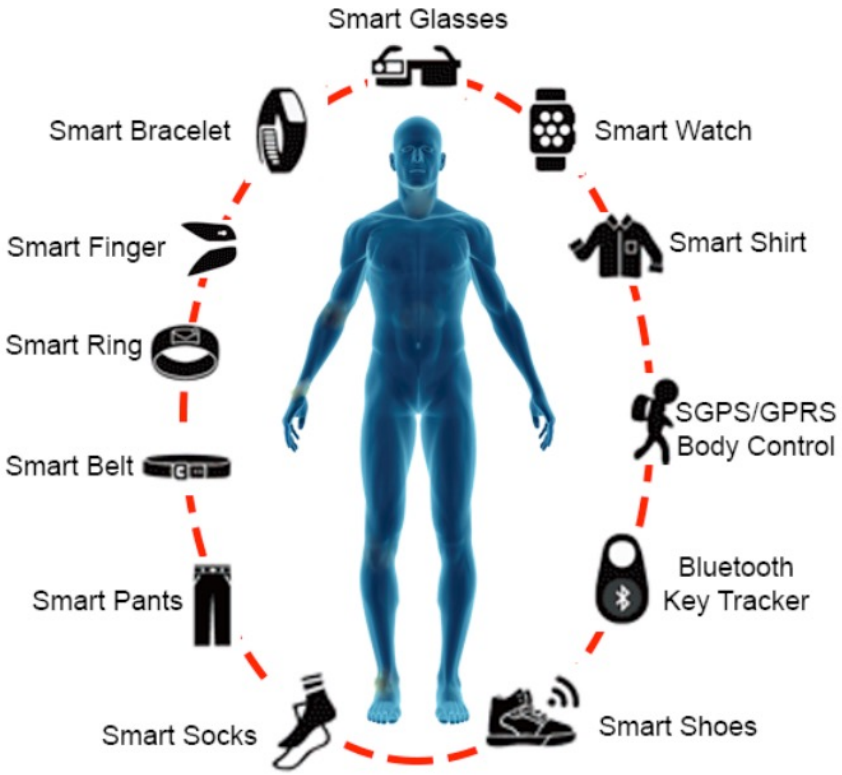
→ Self monitoring was linked to greater weight loss in 74% (50/68) occasions.

Figure 5 Relationship between digital self-monitoring and weight loss, by behavior type. Interventions that reported associations for each self-monitored item separately are represented in the figure in multiple sections rather than in the "combo" section; not all studies with digital self-monitoring reported associations with weight loss for all items that were self-monitored. Combo, a combination of self-monitored items whose engagement level was reported together rather than separately; PA, physical activity. [Color figure can be viewed at wileyonlinelibrary.com]

Obesity, 2021:29(3): 478-499.

Wearable devices

- Electronic device designed to be worn on the user's body
- Detect, analyze, and transmit information
- May be incorporated to physical activity intervention for weight loss



Ieee Access 2018, 6, 13129-13141.

Wearable devices

Wearable technology

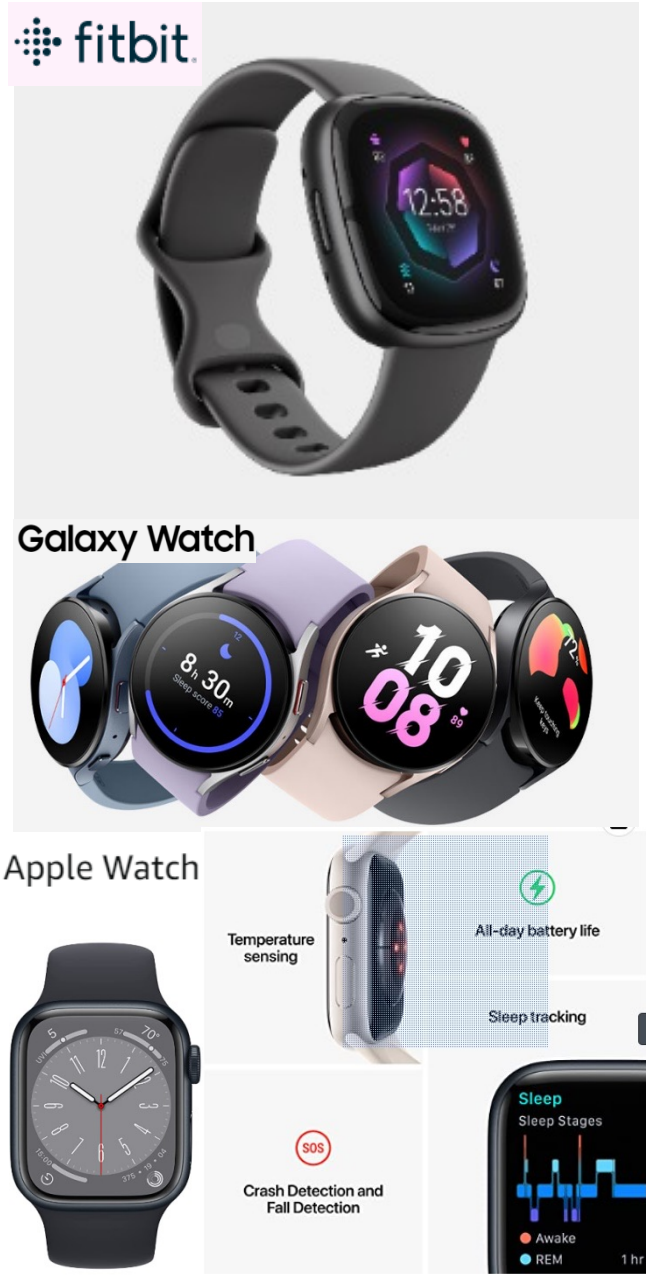
- Pedometer (step counter)
- Accelerometer
- GPS (global positioning system)
- PPG (photoplethysmogram) : optical sensor to measure HR, HRV, SpO2

Ieee Access 2018, 6, 13129-13141.

Wearable devices

Common features (Monitoring)

- Step counts
- Energy expenditure
- Sedentary time
- Heart rate, Temperature, SpO2
- Stress
- Sleep

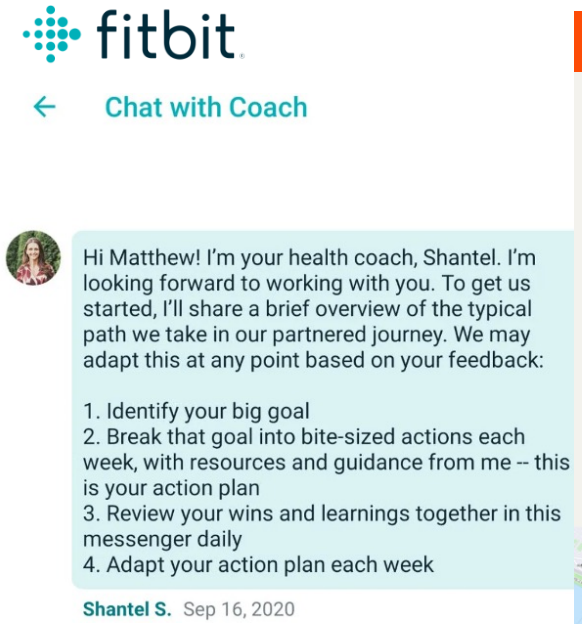


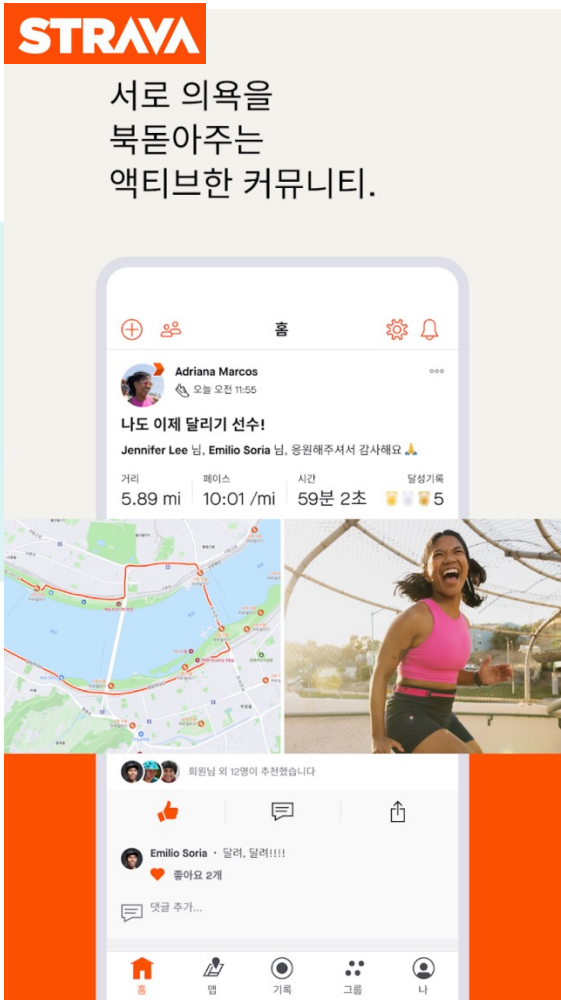
Obesity Reviews. 2019;20:1485–1493.

Wearable devices

Extra features

- Coaching
- In-time feedback
- Social networking
- Competition





Obesity Reviews. 2019;20:1485–1493.

Interventions using wearable technology

Randomized Trial of a Fitbit-Based Physical Activity Intervention for Women

Lisa A. Cadmus-Bertram, PhD, Bess H. Marcus, PhD, Ruth E. Patterson, PhD, Barbara A. Parker, MD, Brittany L. Morey, MPH

BMI ≥25, inactive, postmenopausal women (N=51)
: asked to perform 150 min/wk of MVPA and walk 10,000 steps/day

- **Web-based Tracking Group**: Fitbit + goal-setting, feedback

- **Comparison group**: pedometer + brief goal-setting, tips for increasing steps

MVPA: moderate to vigorous physical activity

PA outcome measure: ActiGraph GT3Xþ

Am J Prev Med., 2015, 49(3): 414-418.

Table 2. Baseline to 16-Week Changes in Objectively Measured Physical Activity and Body Weight

	Web-based tracking group (n=25)				Pedometer group (n=26)				Between-group p-value	Effect size (Cohen's d)
	Baseline	16 weeks	Change	p-value	Baseline	16 weeks	Change	p-value		
Minutes/week of physical activity										
Moderate to vigorous intensity (total)	172 (83)	234 (119)	62 (108)	**0.008**	176 (117)	189 (99)	13 (98)	0.51	0.11	0.48
Moderate to vigorous intensity (in bouts)	24 (39)	62 (82)	38 (83)	**0.01**	42 (68)	57 (69)	16 (76)	0.26	0.28	0.28
Light intensity	1,276 (311)	1,262 (320)	−14 (204)	0.49	1284 (383)	1,252 (317)	−33 (225)	0.82	0.54	0.09
Average steps per day	5,906 (1,968)	6,695 (2,708)	789 (1,979)	**0.01**	5,827 (2,431)	6,188 (2,423)	362 (1,605)	0.17	0.30	0.24
Body weight (kg)	82.4 (14.7)	82.2 (16.0)	−0.3 (2.4)	0.49	79.3 (12.2)	79.2 (13.2)	0.01 (2.3)	0.98	0.61	0.06

Note: Boldface indicates statistical significance (p <0.05).

The Web-Based Tracking Group wore the tracker on 95% of intervention days

Relative to baseline, the Web-Based Tracking Group **increased MVPA and steps,** compared to non-significant increases in the Pedometer Group

Am J Prev Med., 2015, 49(3): 414-418.

Lancet Digit Health 2022;
4: e615–26

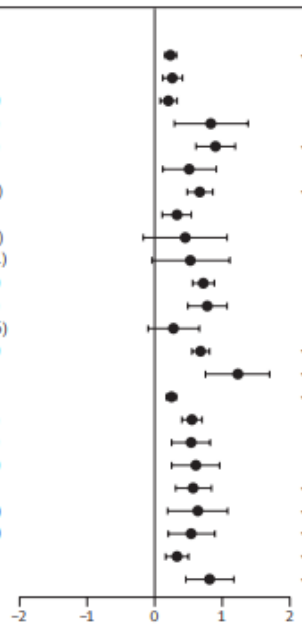
Effectiveness of wearable activity trackers to increase physical activity and improve health: a systematic review of systematic reviews and meta-analyses

Ty Ferguson, Timothy Olds, Rachel Curtis, Henry Blake, Alyson J Crozier, Kylie Dankiw, Dorothea Dumuid, Daiki Kasai, Edward O'Connor, Rosa Virgara, Carol Maher

Systematic review of 37 RCTs

: increase in **daily step count** (1800 per day), **walking time** (40 min per day), **MVPA** (6 min per day)
decrease in **weight** (-1 kg)
small or nonsignificant effect on physiological (BP, lipid profile, A1c) /psychosocial outcome

	Population	Analysis grouping	Number of studies	n	Model	Value (95% CI)	p value	I^2 (%)
Step count								
Brickwood et al, 2019[8]	Mixed*, adults	Overall	11	2144	R, SMD	0·23 (0·15 to 0·32)	<0·0001	3
		SG: MF	7	1210	R, SMD	0·26 (0·12 to 0·41)	0·0004	25
		SG: AT-based	5	934	R, SMD	0·20 (0·08 to 0·33)	0·002	0
Davergne et al, 2019[40]	RMD†, all ages	Overall	7	463	R, SMD	0·83 (0·29 to 1·38)	0·003	85
de Vries et al, 2016[43]	OW OB, adults	Overall	5	417	R, SMD	0·90 (0·61 to 1·19)	<0·001	49
Gal et al, 2018[45]	Mixed*, adults	Overall	7	1392	R, SMD	0·51 (0·12 to 0·91)	0·01	90
		SG: low RoB	3	469	R, SMD	0·67 (0·48 to 0·86)	<0·0001	0
		SG: post-intervention	6	573	R, SMD	0·33 (0·11 to 0·54)	0·003	29
Hannan et al, 2019[47]	Cardiac rehab‡, adults	Overall	4	341	R, SMD	0·45 (−0·17 to 1·07)	0·15	81
Kang et al, 2009[49]	Mixed*, all ages	Overall	32	2570	R, G	0·53 (−0·04 to 1·11)	..	..
		SG: combined ages	5	307	R, G	0·72 (0·56 to 0·88)	..	..
		SG: children	10	296	R, G	0·78 (0·49 to 1·07)	..	..
		SG: adults	32	1924	R, G	0·28 (−0·10 to 0·66)	..	..
		SG: older adults	3	43	R, G	0·68 (0·55 to 0·81)	<0·001	77
Liu et al, 2020[53]	General, older adults	Overall	2	83	R, SMD	1·23 (0·75 to 1·70)	<0·0001	0
Lynch et al, 2020[55]	General, adults	Overall	2	904	F, SMD	0·25 (0·17 to 0·32)	<0·01	57
Oliveira et al, 2020[59]	Mixed*, older adults	Overall	23	2766	R, SMD	0·55 (0·40 to 0·70)	0	85·8
		SG: clinical conditions	14	..	R, SMD	0·54 (0·25 to 0·82)	0·001	..
		SG: general population	9	..	R, SMD	0·61 (0·25 to 0·96)	0·002	..
Qiu et al, 2019[9]	COPD, adults	Overall	15	644	R, SMD	0·57 (0·31 to 0·84)	<0·05	75
		SG: AT + PR vs PR	6	146	R, SMD	0·64 (0·19 to 1·08)	<0·05	64
		SG: AT vs usual care	9	498	R, SMD	0·54 (0·20 to 0·89)	<0·05	81
Tang et al, 2020[66]	Healthy, adults	Overall	7	543	F, SMD	0·33 (0·16 to 0·50)	<0·001	2
Vaes et al, 2013[68]	T2DM, adults	Overall	8	633	R, SMD	0·81 (0·46 to 1·17)	<0·0001	73



Lancet Digit Health 2022; 4: e615–26

Newer technologies

Virtual reality

- Eating behavior : avoiding or coping with specific situation specific environmental situation (ex. food cue)
- Body image : overcoming distorted perception of body (ex. acceptance through confrontation) motivation for weight loss through virtual ideal self

Virtual Reality in Eating Disorders and Obesity

Posted On: 4th June 2014

➢ By Giuseppe Riva & Enrico Molinari

Figure 1: A patient undergoes experiential cognitive therapy

30.09.2019 · #GAMIFICATION #MENTAL HEALTH #THERAPY

Virtual reality: Avatars against obesity

A collaborative project develops virtual reality methods to positively affect the body perception of obese patients.

Obesity, which means having a high amount of extra body fat, is a widespread medical condition that affects more than 20 percent of the German population. Obesity is also a global epidemic: It is the number six cause of death in the world.

People struggling with obesity are often at war with their own bodies. A lot of them have stopped believing that they are able to lose weight at all. This state of discontentment can also have an impact on the social life and the mental health of

Cyberpsychology, Behavior, and Social Networking > VOL. 19, NO. 2 | Original Articles normal

The Power of the Virtual Ideal Self in Weight Control: Weight-Reduced Avatars Can Enhance the Tendency to Delay Gratification and Regulate Dietary Practices

Hsu-Chan Kuo, Chun-Chia Lee, and Wen-Bin Chiou

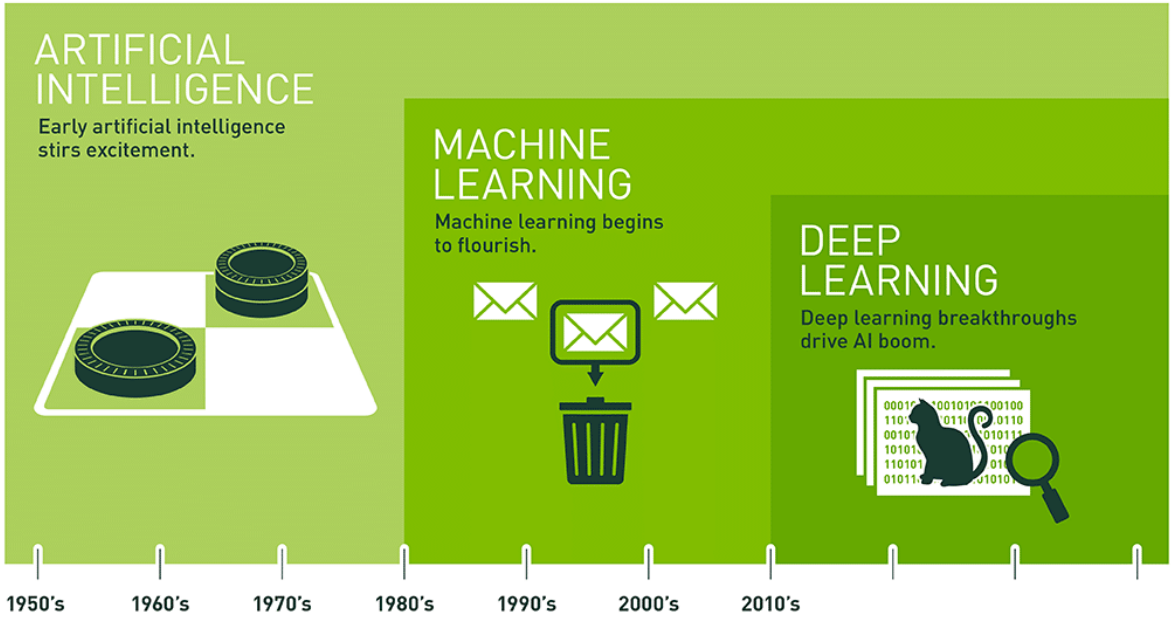
Published Online: 16 Feb 2016 | https://doi.org/10.1089/cyber.2015.0203

J Med Internet Res 2018;20(4):e157

Newer technologies

Artificial intelligence technologies

- Mimicry of human intelligence through machine learning to attain and apply knowledge and skills
- Identifies individualized weight loss predictors and reinforces learning based on continuously collected data → optimization of personalized approach



Since an early flush of optimism in the 1950s, smaller subsets of artificial intelligence – first machine learning, then deep learning, a subset of machine learning – have created ever larger disruptions.

J Behav Med (2019) 42:276–290: Public Health Nutr. 2021 Jun; 24(8): 1993–2020

Potential benefits of DTx

- Easier access
- Real-time monitoring and interaction
- Improve adherence rate
- Enhance cost-effectiveness
- Patient data collection and analysis
- Personalized approach
- Enhance the quality of management

Endocrinol Metab 2021;36:220-228

Clinical evidences

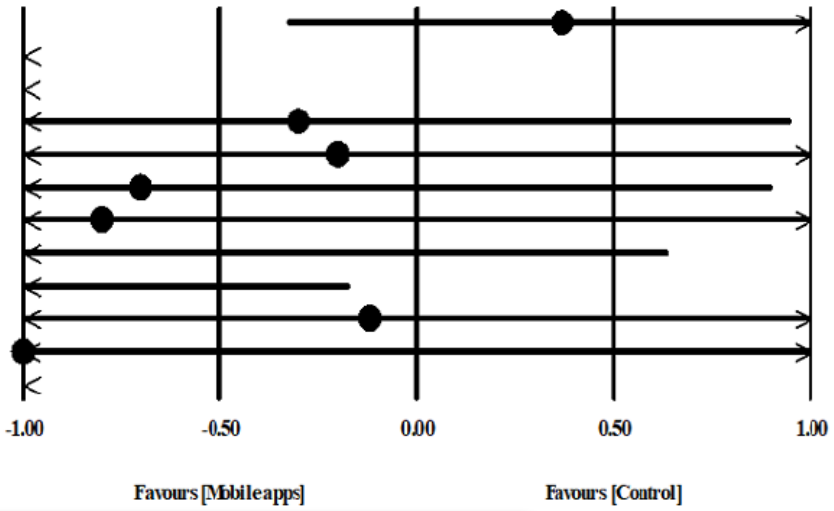
Original Paper

Use of Mobile Phone App Interventions to Promote Weight Loss: Meta-Analysis

Md Mohaimenul Islam[1,2,3], MSc; Tahmina Nasrin Poly[1,2,3], MSc; Bruno Andres Walther[4], PhD; Yu-Chuan (Jack) Li[1,2,3,5], PhD

Study name	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z value	*P* value	Relative weight
Patel 2019	0.370	0.357	0.127	-0.329	1.069	1.037	.30	12.41
Farinelli 2016	-3.000	0.551	0.303	-4.080	-1.920	-5.447	.00	11.13
Partridge 2015	-2.100	0.369	0.136	-2.823	-1.377	-5.693	.00	12.34
Laing 2014	-0.300	0.637	0.406	-1.549	0.949	-0.471	.63	10.50
Hebden 2014	-0.200	0.865	0.749	-1.896	1.496	-0.231	.81	8.83
Glynn 2014	-0.700	0.817	0.668	-2.302	0.902	-0.857	.39	9.18
Brindal 2013	-0.800	1.183	1.399	-3.119	1.519	-0.676	.49	6.78
Carter 2013	-1.700	1.194	1.425	-4.039	0.639	-1.424	.15	6.72
Allen 2013	-2.900	1.393	1.940	-5.630	-0.170	-2.082	.03	5.69
McGrievy 2011	-0.120	0.740	0.548	-1.571	1.331	-0.162	.87	9.74
Lee 2010	-1.000	1.201	1.441	-3.353	1.353	-0.833	.40	6.68
Random effect:	-1.073	0.436	0.190	-1.928	-0.218	-2.459	.01	

Heterogeneity: I^2=76.55, Q=42.65, tau^2=1.40, p<.01



12 studies, overweight or obese participants
mobile phone app intervention vs control (heterogeneous)

Weight loss difference
Body weight −1.07 kg
BMI −0.45 kg/m²

JMIR mhealth uhealth. 2020;8(7):e17039

Web-Based Digital Health Interventions for Weight Loss and Lifestyle Habit Changes in Overweight and Obese Adults: Systematic Review and Meta-Analysis

Figure 6. Meta-analysis results for mean weight change (kg) in Web-based-only versus nonactive interventions (wait list) in the control group. df: degrees of freedom; IV: interval variable; random: random effects model.

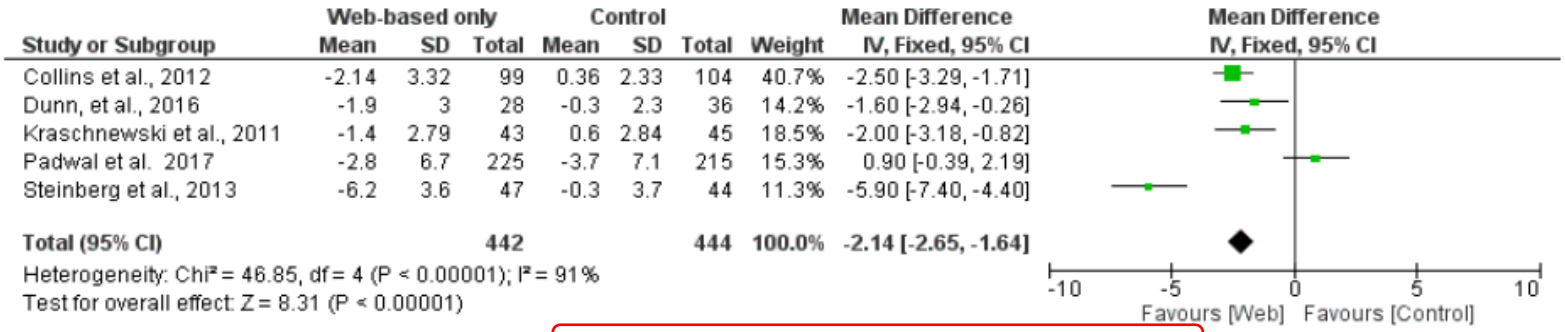


Figure 7. Meta-analysis results for mean weight change (kg) in Web-based-only versus offline interventions for studies with <6 months follow-up duration. df: degrees of freedom; IV: interval variable; random: random effects model.

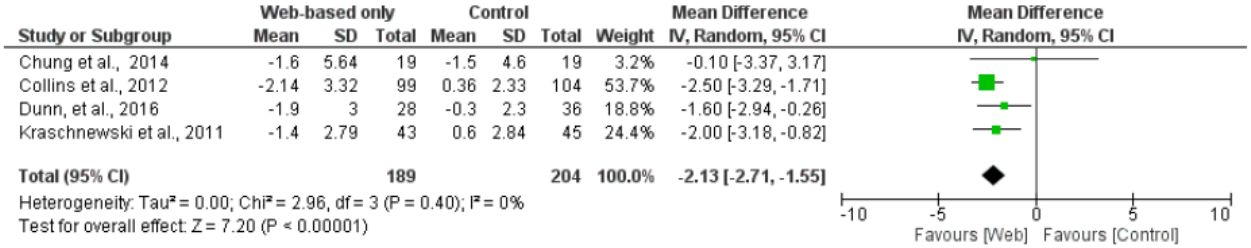
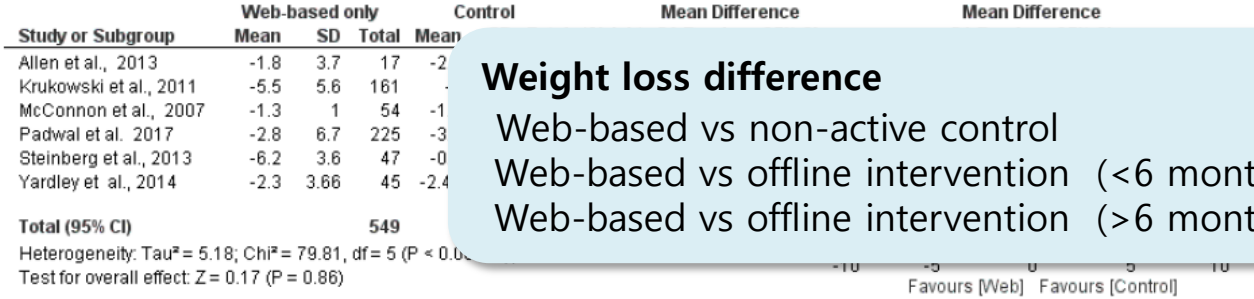


Figure 8. Meta-analysis results for mean weight change (kg) in Web-based-only versus offline interventions for studies with ≥6 months follow-up duration. df: degrees of freedom; IV: interval variable; random: random effects model.



Weight loss difference

Web-based vs non-active control	- 2.14 kg
Web-based vs offline intervention (<6 months)	- 2.13 kg
Web-based vs offline intervention (>6 months)	no difference

ICT-based intervention vs conventional therapy

- A meta-analysis (2019) showed that the weight loss effect was inferior when using only ICT-based interventions compared to conventional (face-to-face) behavioral therapy (0.82 kg; 95% CI, 0.06–1.59)

J Med Internet Res 2019;21:e298

- In a meta-analysis (2021), ICT-based interventions had an effect on weight loss but it was not statistically significant compared to that of general treatment (–0.56 kg; 95% CI, –3.74 to 4.59; *P*=0.786)

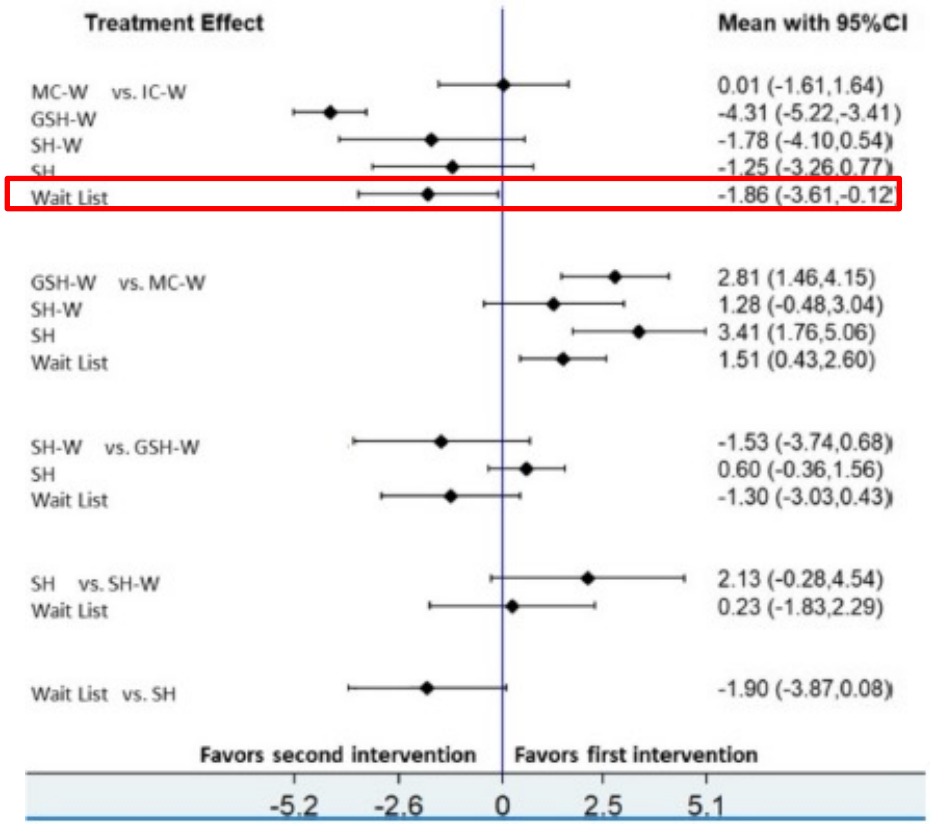
J Health Popul Nutr 2021;40:16

ICT-based intervention combined with conventional therapy

REVIEW Open Access

Effectiveness of web-based feedback interventions for people with overweight and obesity: systematic review and network meta-analysis of randomized controlled trials

Carmen Varela[1], Camila Oda-Montecinos[2], Ana Andrés[3] and Carmina Saldaña[1,4*]



SH, Self-Help
SH-W, Self-Help Web
GSH-W, Guided Self-Help Web
MC-W, Minimal Contact Web
IC –W, Intensive Contact Web

Network meta-analysis of 15 RCTs

IC–W
(Intensive Contact Web-based interventions)

→ **-1.86 kg** loss compared to wait list
→ obtained the **first position** in the ranking.

J Eat Disord., 2021, 9(1): 1-14

JAMA | Original Investigation

Effect of an Online Weight Management Program Integrated With Population Health Management on Weight Change
A Randomized Clinical Trial

Heather J. Baer, ScD; Ronen Rozenblum, PhD, MPH; Barbara A. De La Cruz, BA; E. John Orav, PhD; Matthew Wien, BS; Nyryan V. Nolido, MA; Kristina Metzler, MS; Katherine D. McManus, MS; Florencia Halperin, MD; Louis J. Aronne, MD; Guadalupe Minero, MPH; Jason P. Block, MD, MPH; David W. Bates, MD, MSc

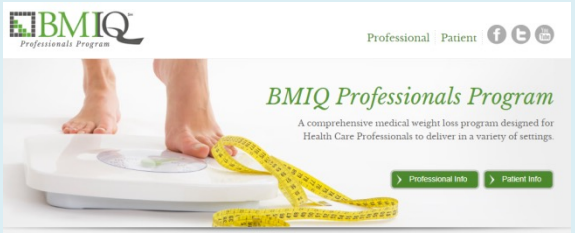
Question Does a combined intervention, including an online weight management program integrated with population health management (additional support and outreach from nonclinical staff), increase weight loss at 12 months among primary care patients compared with the online program only and usual care?

BMI 27-40, hypertension or T2DM patients
(N=840, from 15 primary care practices in the US)

Intervention: 12 months
Outcome: weight change at 12 months, 18 months

Usual care (N=326)
- Mailed general information about diet and physical activity

Online program only (N=216)
- Online weight management program (BMIQ, *Intellihealth Inc*)



Combined intervention group (N=298)
- Online weight management program (BMIQ, *Intellihealth Inc*)
- Support from population health manager who monitored and encouraged their progress

JAMA. 2020 Nov 3;324(17):1737-1746

Table 2. Mean Changes in Weight-Related Outcomes

	Combined intervention	Online program only	Usual care	P value
No. of total participants	298	216	326	
Primary analysis: changes from baseline to 12 mo[a]				
Weight, kg				
At baseline	92.1	91.4	92.3	
Change at 12 mo (95% CI)	-3.1 (-3.7 to -2.5)	-1.9 (-2.6 to -1.1)	-1.2 (-2.1 to -0.3)	<.001[b]
Weight change at 12 mo, % (95% CI)	-3.0 (-3.8 to -2.1)	-1.9 (-2.8 to -1.0)	-1.4 (-2.3 to -0.6)	<.001[b]
Participants had ≥5% weight loss at 12 mo, % (95% CI)	32.3 (25.8 to 38.8)	20.8 (14.5 to 27.2)	14.9 (10.2 to 19.6)	<.001[b]
Confidence in ability to lose weight, points[c]				
At baseline	6.5	6.8	6.8	
Change at 12 mo (95% CI)	0.5 (0.06 to 0.9)	-0.4 (-0.9 to 0.07)	-0.7 (-1.1 to-0.3)	<.001[b]
Secondary analysis: changes over entire 18-mo follow-up period[d]				
Weight, kg				
At baseline	92.1	91.4	92.3	<.001[e]
Change at 6 mo (95% CI)	-2.9 (-3.5 to -2.3)	-2.1 (-2.8 to -1.5)	-1.0 (-1.9 to -0.1)	
Change at 12 mo (95% CI)	-3.1 (-3.7 to -2.5)	-1.9 (-2.6 to -1.1)	-1.2 (-2.1 to -0.3)	
Change at 18 mo (95% CI)	-2.8 (-3.5 to -2.0)	-1.1 (-2.0 to -0.3)	-1.9 (-2.8 to -1.0)	
Weight change, % (95% CI)				
At 6 mo	-2.8 (-3.8 to -1.8)	-2.0 (-3.1 to -0.9)	-1.0 (-1.9 to 0.03)	.01[e]
At 12 mo	-2.9 (-3.9 to -2.0)	-1.7 (-2.8 to -0.6)	-1.2 (-2.1 to -0.2)	
At 18 mo	-2.6 (-3.6 to -1.5)	-0.9 (-2.0 to 0.2)	-1.9 (-2.9 to -0.9)	
Participants lost ≥5% of body weight, % (95% CI)				
At 6 mo	29.5 (21.4 to 37.5)	22.1 (14.2 to 30.0)	13.4 (7.8 to 19.0)	.20[e]
At 12 mo	31.5 (23.4 to 39.5)	20.4 (13.0 to 27.9)	12.7 (7.7 to 17.7)	
At 18 mo	31.3 (23.0 to 39.6)	19.9 (12.5 to 27.3)	20.9 (14.3 to 27.6)	
Aggregate estimate across all 3 time points	30.7 (22.4 to 39.0)	20.8 (13.0 to 28.6)	15.7 (6.2 to 25.1)	<.001[e]

Combining population health management with an online program
→ **small but statistically significant greater amount of weight loss** compared with usual care or the online program only.

JAMA. 2020 Nov 3;324(17):1737-1746

JAMA Network Open

Original Investigation | Psychiatry

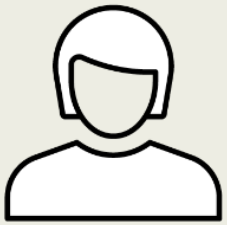
Effectiveness of a Digital Cognitive Behavior Therapy–Guided Self-Help Intervention for Eating Disorders in College Women

A Cluster Randomized Clinical Trial

Ellen E. Fitzsimmons-Craft, PhD; C. Barr Taylor, MD; Andrea K. Graham, PhD; Shiri Sadeh-Sharvit, PhD; Katherine N. Balantekin, PhD, RD; Dawn M. Eichen, PhD; Grace E. Monterubio, MA; Neha J. Goel, MS; Rachael E. Flatt, MA; Anna M. Karam, PhD; Marie-Laure Firebaugh, LMSW; Corinna Jacobi, PhD; Booil Jo, PhD; Mickey T. Trockel, MD, PhD; Denise E. Wilfley, PhD

POPULATION

690 Women



Adult female university students with a *DSM-5* bingeing or purging eating disorder (excluding anorexia nervosa) identified through online screening

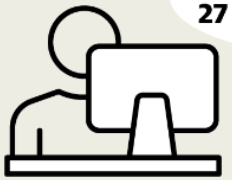
Mean (SD): 22.12 (4.85) y

SETTINGS / LOCATIONS

28 US universities

INTERVENTION

28 Universities randomized
27 Analyzed



13 Student Bodies-Eating Disorders program

Digital CBT-guided self-help (educational content, meal planning/tracking tools, self-monitoring logs, coach texting) (385 women)

14 Referral to usual care

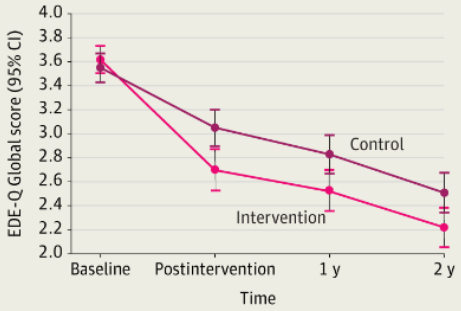
Referral to on-campus counseling center (305 women)

PRIMARY OUTCOME

Change in eating disorder psychopathology based on the Eating Disorder Examination-Questionnaire (EDE-Q) Global score after intervention and at 1 and 2 y (range 0-6, higher score = more severe eating disorder)

FINDINGS

There was greater reduction in eating disorder psychopathology (EDE-Q score) in women exposed to the intervention vs control



Standardized mean difference EDE-Q score (Cohen *d*)
Postintervention: 0.40 ($P < .001$)
Follow-up (1 and 2 y): 0.35 ($P < .001$)

EDE-Q Mean Score	EDE-Q Mean Score
Baseline: 3.62	Baseline: 3.55
Postintervention: 2.70	Postintervention: 3.05
1 y: 2.55	1 y: 2.83
2 y: 2.22	2 y: 2.51

Fitzsimmons-Craft EE, Taylor CB, Graham AK, et al. Effectiveness of a digital cognitive behavior therapy-guided self-help intervention for eating disorders in college women: a cluster randomized clinical trial. *JAMA Netw Open*. 2020;3(8):e2015633. doi:10.1001/jamanetworkopen.2020.15633

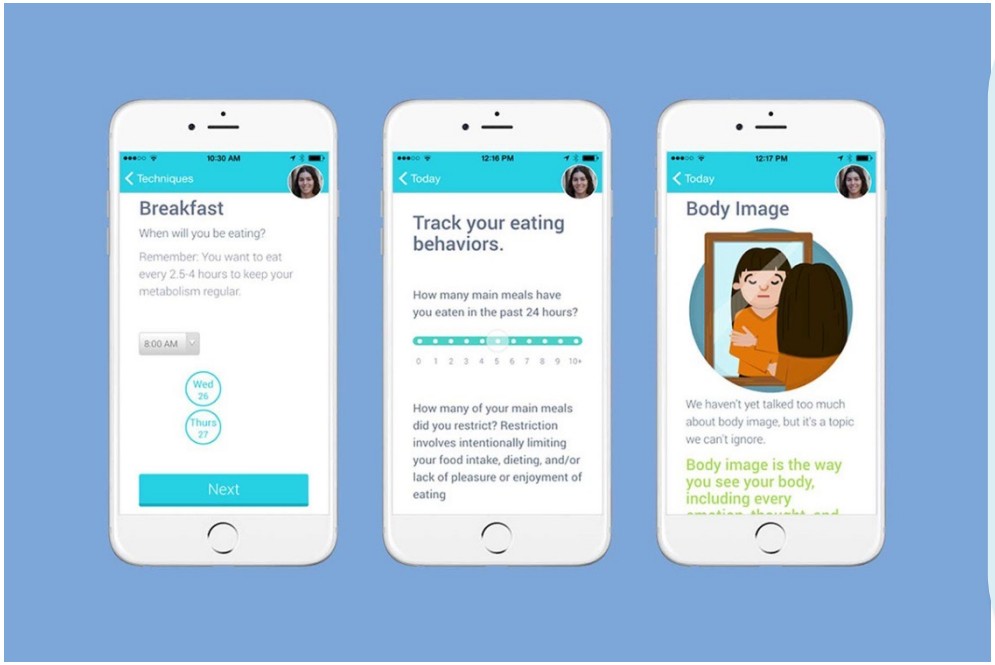
Student Bodies–Eating Disorders (SB-ED)

- Digital cognitive behavioral therapy (CBT)–guided self-help program

+

Personal coach (under supervision of clinical psychologist)

- Timely messages, support, feedback



Core components of CBT for EDs

Reducing ED behaviors

(via self-monitoring, regular eating)

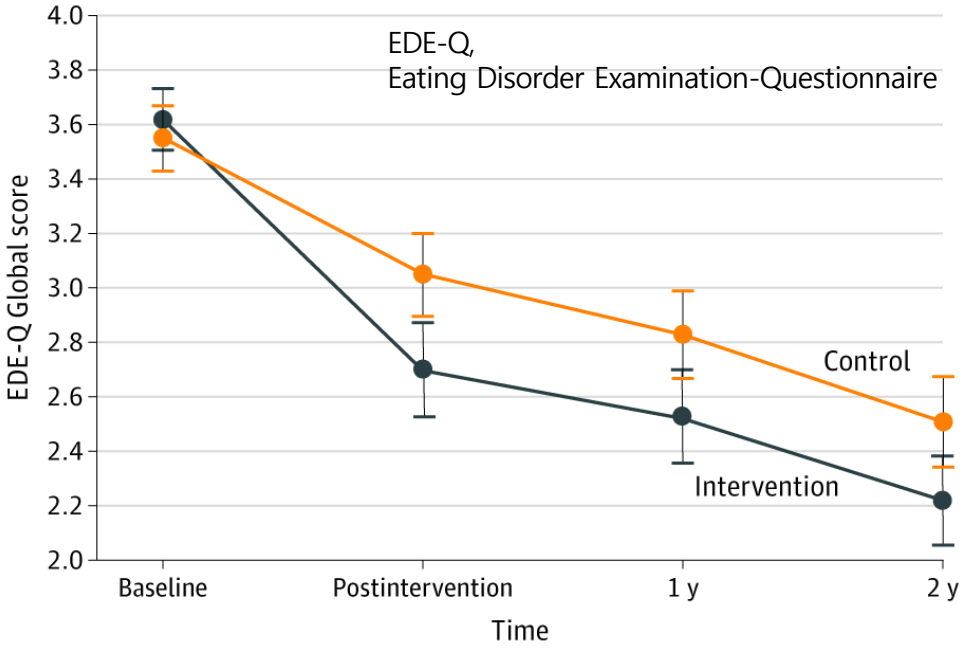
Improving body image

Regulating emotions

Challenging negative thoughts

Preventing relapse

JAMA Netw Open. 2020 Aug 3;3(8):e2015633



Intervention group had **greater improvements** in..

ED psychopathology
ED behaviors
depression
clinical impairment

Table 3. Estimated Effects of Intervention on Outcome Measures[a]

Outcome measures	Intervention effect, β (SE)		Intervention effect					
			Postintervention assessment			Follow-up		
	Postintervention assessment	Follow-up	t_{1387}	*P* value	Effect size (*d*)	t_{1387}	*P* value	Effect size (*d*)
Continuous measures								
Eating Disorder Examination-Questionnaire	−0.44 (0.10)	−0.39 (0.12)	−4.23	<.001	−0.40	−3.30	<.001	−0.35
Patient Health Questionnaire-9	−1.34 (0.53)	−1.28 (0.40)	−2.52	.01	−0.22	−3.18	.001	−0.21
Patient-Reported Outcomes Measurement Information System anxiety short-form	−0.65 (0.35)	−0.84 (0.32)	−1.86	.06	−0.15	−2.64	.008	−0.20
Clinical Impairment Assessment	−2.33 (0.94)	−3.19 (1.06)	−2.49	.01	−0.21	−3.01	.003	−0.28
Eating disorder behaviors, rate ratio (95% CI)[b]								
Abstinence (binary)	1.48 (0.48-4.62)	1.51 (0.63-3.58)	0.68[c]	.50		0.92[c]	.36	
Binge eating (rate)	0.82 (0.70-0.96)	0.81 (0.65-1.00)	−2.42[c]	.02		−1.94[c]	.05	
All compensatory behaviors (rate)[d]	0.68 (0.54-0.86)	0.76 (0.60-0.98)	−3.26[c]	<.001		−2.11[c]	.04	

[a] A logit link was specified in the mixed effects model assessing effects on abstinence. A log link was specified in mixed effects models assessing effects on binge eating and compensatory behavior rates.

[b] Eating disorder behaviors included binge eating episodes, or compensatory behaviors involving vomiting, laxatives, and/or excessive exercise in the past 28 days.

[c] The *df* for these *t* statistics is 1392.

[d] All compensatory behaviors is the sum of frequency counts of compensatory behaviors in the past 28 days, including vomiting, laxative use, and excessive exercise.

Summary of current evidences

- Technology based interventions have shown their effectiveness in obesity management.

- However, there are limitations
  - **Continuity** of participation
  - **Effect size** is small
  - **Comparative benefit** to face-to-face treatment is **controversial**

- Technology based interventions have **additive effect** to conventional treatment.

- Further research is needed to clarify
  - Long term (>1 year) efficacy
  - Efficacy in diversified population
  - Cost-effectiveness

Considerations for adoption

Concerns for adoption of DTx

Viewpoint

September 22, 2022

Unsettled Liability Issues for "Prediagnostic" Wearables and Health-Related Products

David A. Simon, JD, LLM, PhD[1]; Carmel Shachar, JD, MPH[1]; I. Glenn Cohen, JD[1]

» Author Affiliations | Article Information

JAMA. 2022;328(14):1391-1392. doi:10.1001/jama.2022.16317

Prediagnostic products and other health-related applications are bringing exciting technologies directly to consumers....But these products also present a context that is rife with legal uncertainty for all.

JAMA. 2022;328(14):1391-1392

- Liability Issues: legal gray area?
- Process surrounding the evaluation
- Cybersecurity and data rights
- Finance and reimbursement
- Needs of diverse populations

Forbes 2020. 2, "Digital Therapeutics Leaders Focus On Reimbursement"
BCG. 2020. 8, "Can Digital Therapeutics Help Deliver Health Care Equality?"

GDHP

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A Global Commitment to Digital Health

The Global Digital Health Partnership (GDHP) is a collaboration of country governments, territory governments, and international organizations formed to support the executive implementation of worldwide digital health services.

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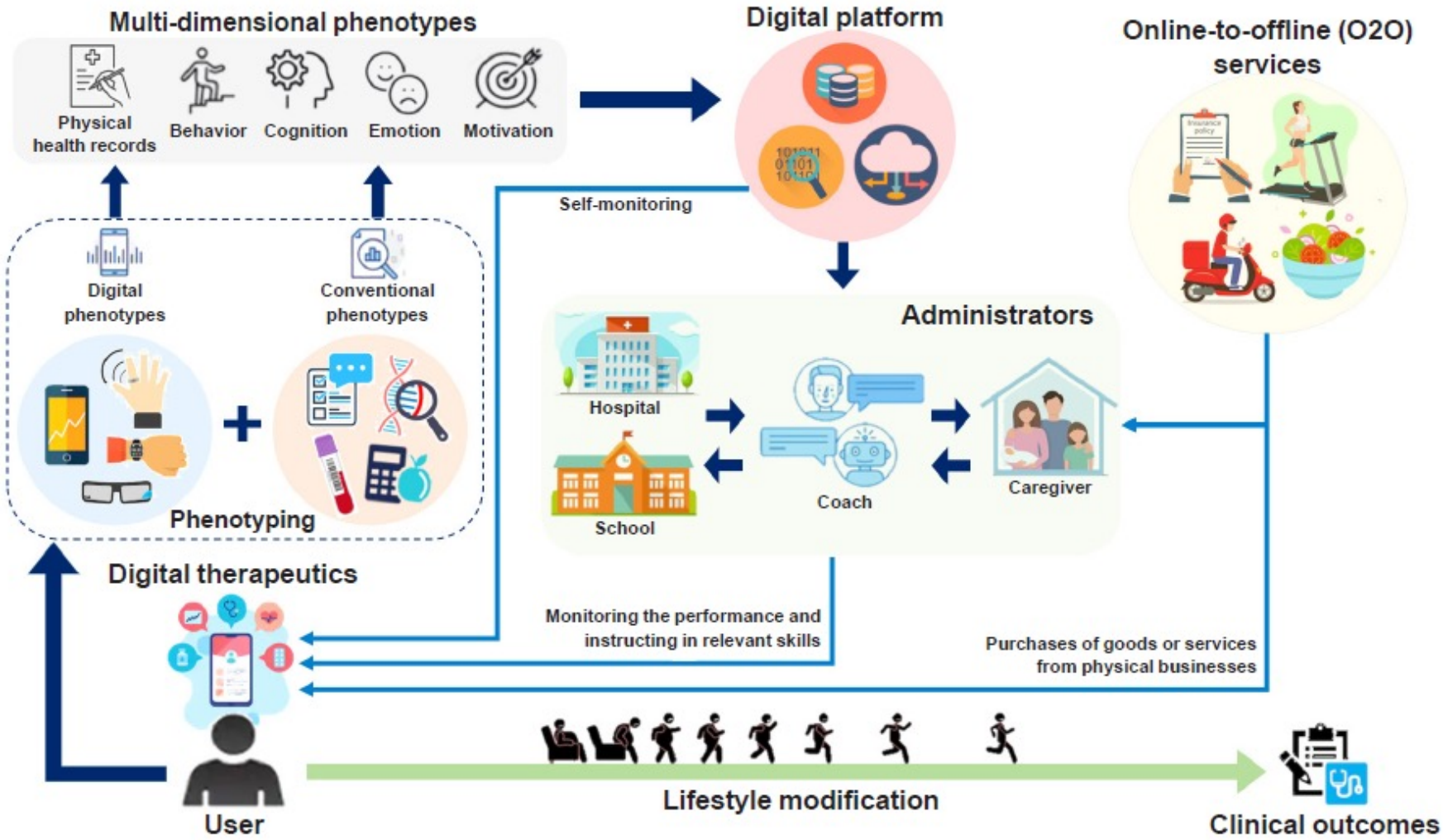

Fig. 3. Future perspectives for the ecological environment of digital therapeutics.

Take home message

- Benefits of technology based interventions
  - Access, Efficiency, Personalized approach

- Clinical evidence
  - Potential as adjuncts to conventional interventions
    or low-intensity intervention
    rather than as intensive stand-alone treatment.

- Concerns
  - Long-term adherence, effect size
  - Legal, financial, administrative issues

- Future perspective
  - Newer technologies, evolution of ecological environment
    → Multidimensional, personalized management