SOMS
The Study of Obesity and Metabolic Syndrome

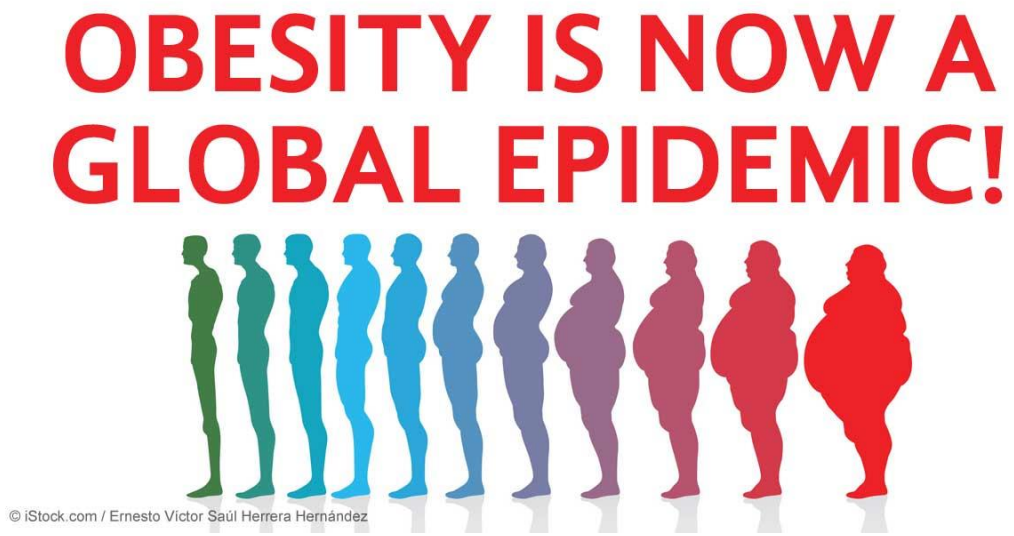
Digital Therapeutics for Obesity Care

Obesity management using ICT

Yoobin Seo
Wonkwang University Sanbon Hospital

Contents

Obesity epidemic



WHO fact sheet

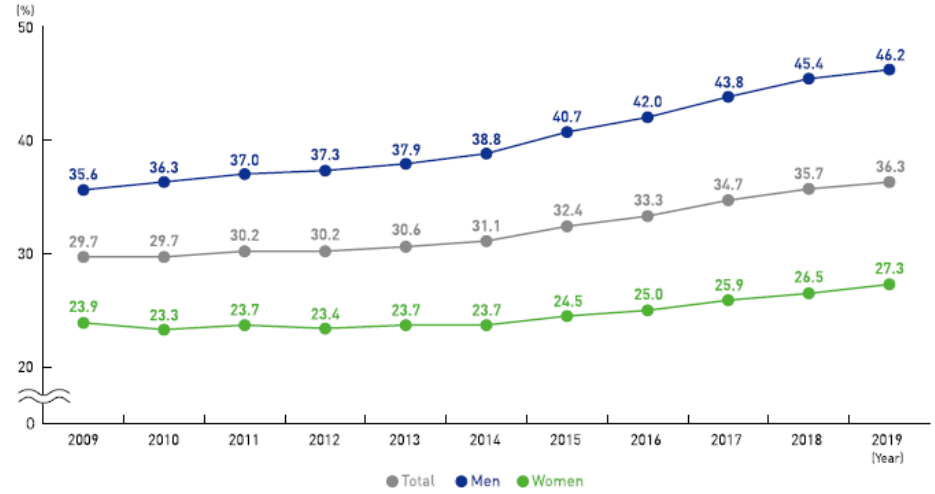
- Worldwide obesity has nearly tripled since 1975.
- 39% of adults were overweight and 13% were obese in 2016.
- Most of the world's population live in countries where overweight and obesity kills more people than underweight.
- 2.8 million people dying each year as a result of being overweight or obese.

Obesity epidemic in Korea

2021 Obesity fact sheet

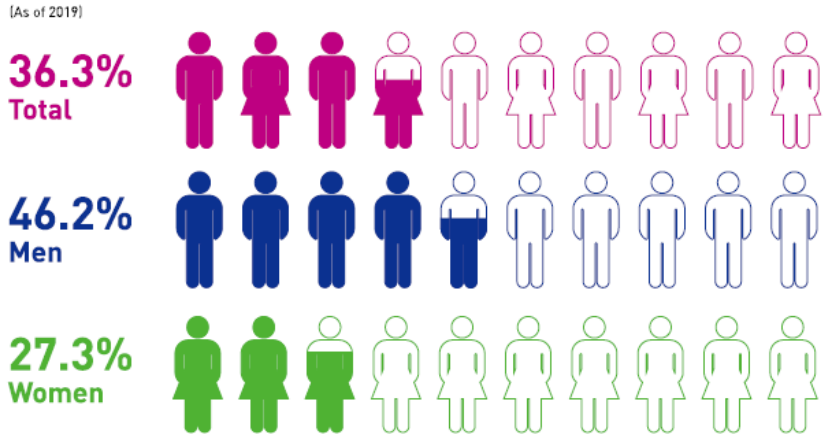
Prevalence of obesity in the last 11 years

The prevalence of obesity has steadily increased over the past 11 years, especially in men.
In 2019, the prevalence of obesity was 36.3% in the total population: 46.2% in men and 27.3% in women.



- The prevalence was standardized by age and sex, based on the 2010 Population and Housing Census data from the Statistics of Korea.
- The 2009-2019 NHIS health checkup data were analyzed.

Prevalence of obesity in 2019



- The prevalence was standardized by age and sex, based on the 2010 Population and Housing Census data from the Statistics of Korea.
- The 2009-2019 NHIS health checkup data were analyzed.

Korean society for the study of obesity

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

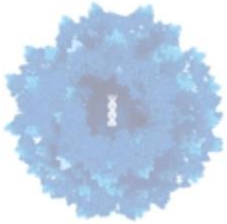
medium.com/@mebrin/ibesity-713346b714ec

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

SMALL MOLECULES

BIOLOGICS

CELL/GENE THERAPIES



DIGITAL THERAPEUTICS

1900 // 1990 2000 2010 2017 & Beyond

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]

American Diabetes Association

Standards of Care in Diabetes—2023

Digital Health Technology

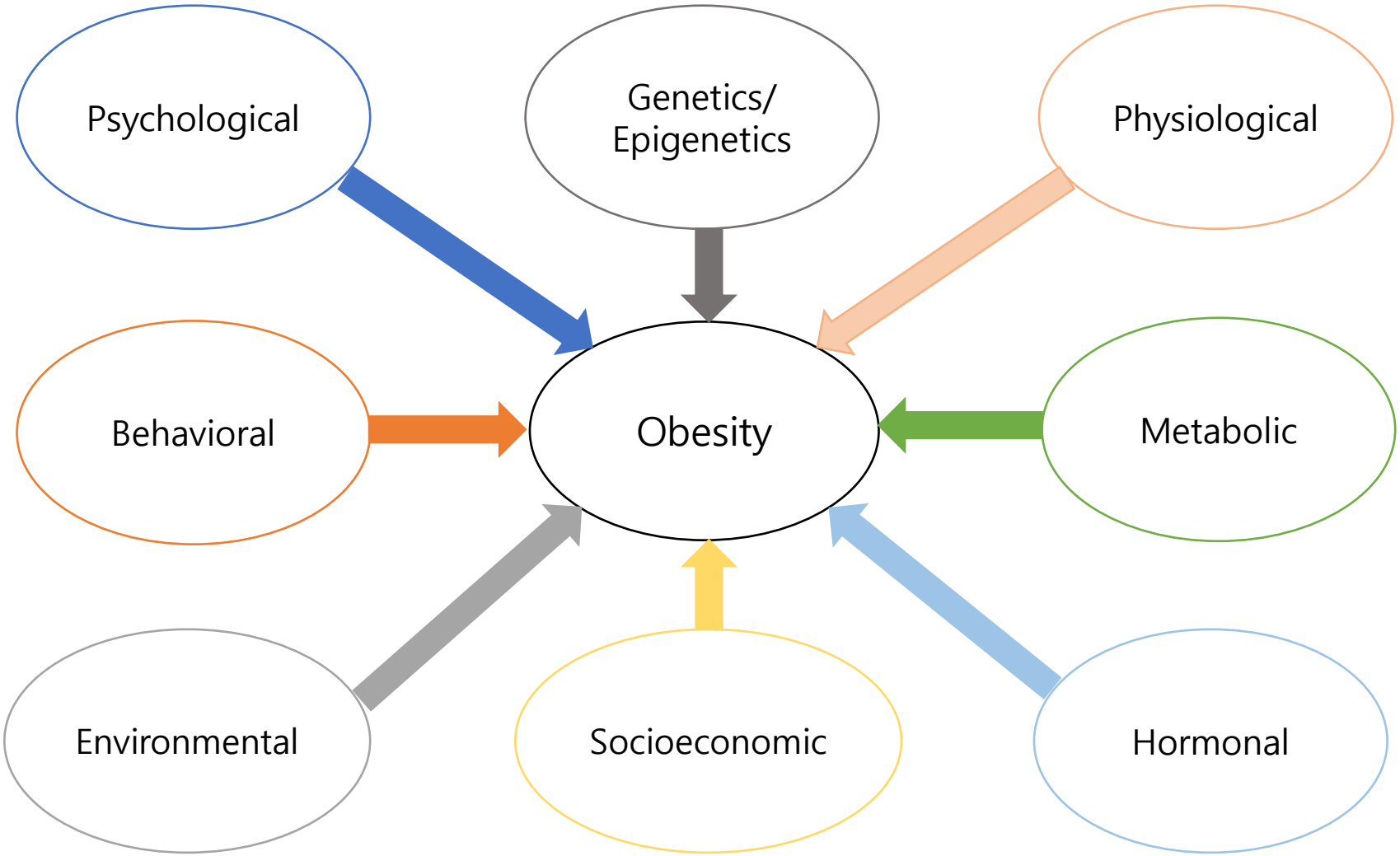
Recommendation

7.29 Systems that combine technology and online coaching can be beneficial in treating prediabetes and diabetes for some individuals. **B**

5.5 Digital coaching and digital self-management interventions can be effective methods to deliver diabetes self-management education and support. **B**

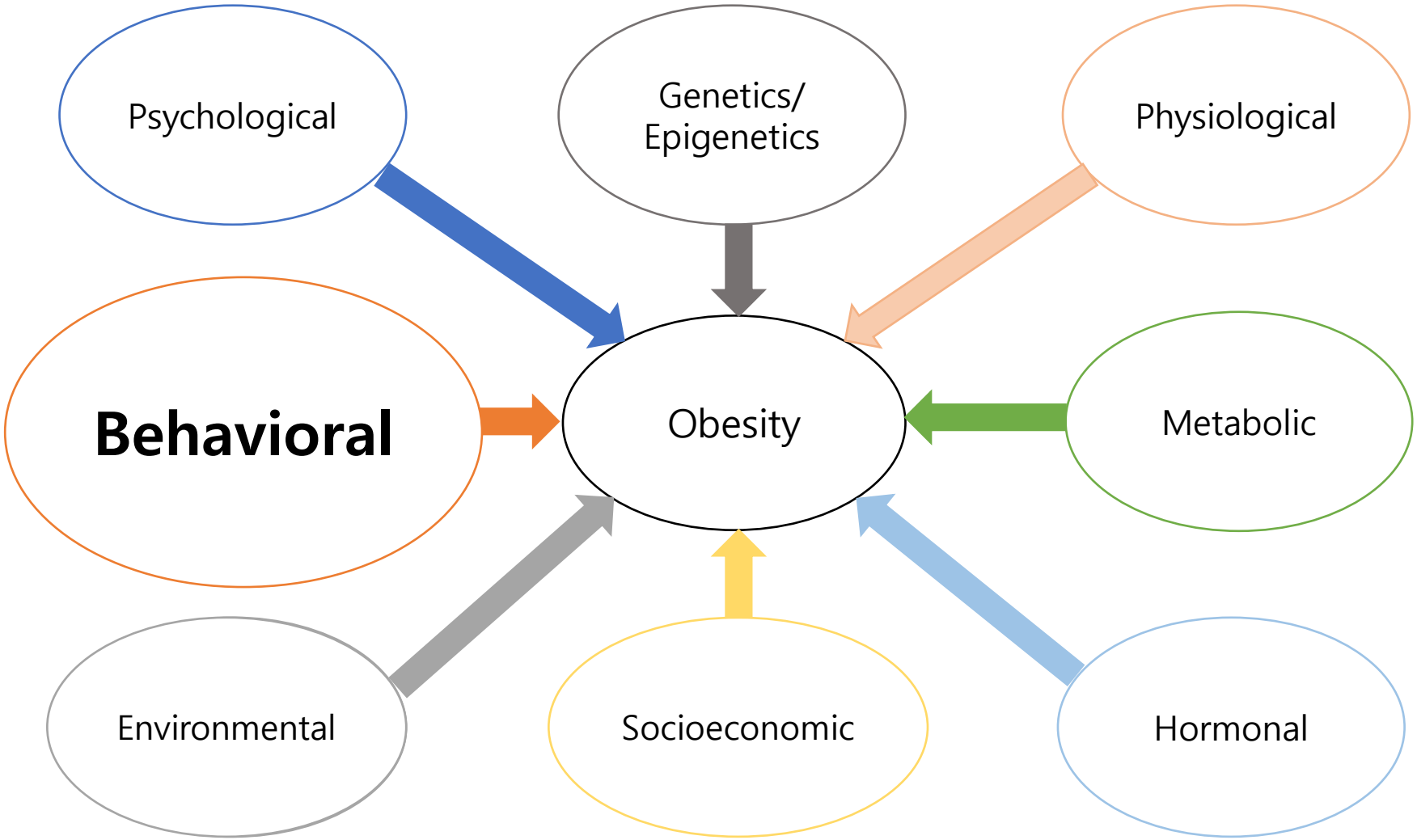
Technology-enabled diabetes self-management solutions improve A1C most effectively when there is two-way communication between the person with diabetes and the health care team, individualized feedback, use of person-generated health data, and education (46). Continuous glucose monitoring, when combined with individualized diabetes education or behavioral interventions, has demonstrated greater improvement on glycemic and psychosocial outcomes compared with continuous glucose monitoring alone (63,64). Incorporating a systematic approach for technology assessment, adoption, and integration into the care plan may help ensure equity in access and standardized application of technology-enabled solutions (8, 30,65–67).

Multifactorial etiology of obesity



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

Multifactorial etiology of obesity



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

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

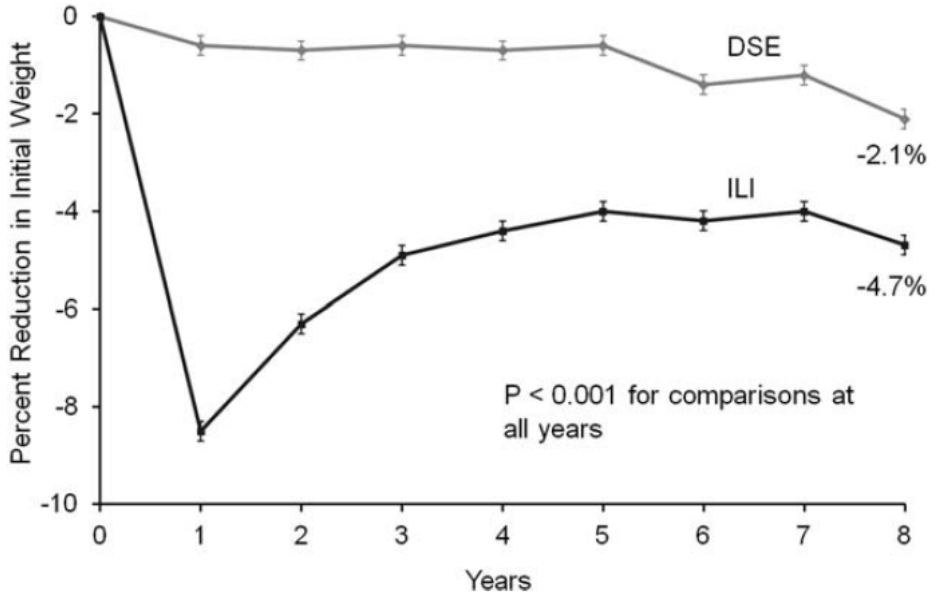


Figure 2 Figure shows mean (±SE) weight losses over 8 years for participants randomly assigned to an intensive lifestyle intervention (ILI) or diabetes support and education (DSE; usual care group). Differences between groups were significant ($P < 0.001$) at all years.

DSE : diabetes support and education

ILI : intensive lifestyle intervention

→ 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 2014; 22, 5-13

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

DIABETES PREVENTION PROGRAM RESEARCH GROUP*

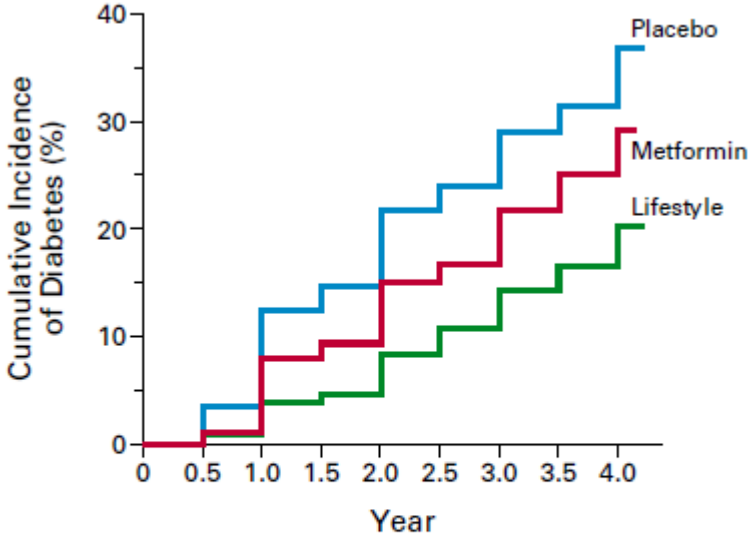


Figure 2. Cumulative Incidence of Diabetes According to Study Group.

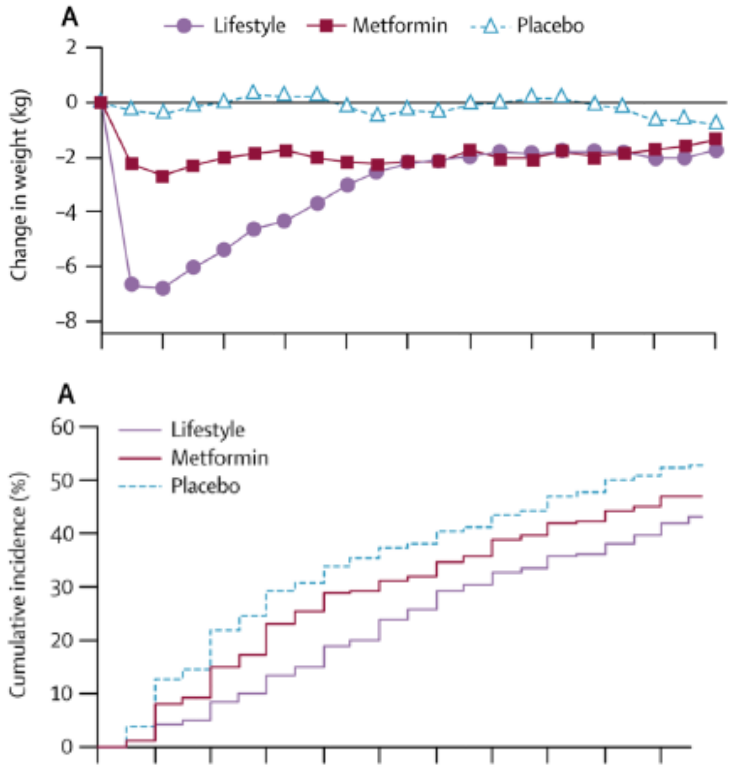
The diagnosis of diabetes was based on the criteria of the American Diabetes Association.[11] The incidence of diabetes differed significantly among the three groups ($P<0.001$ for each comparison).

→ 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.

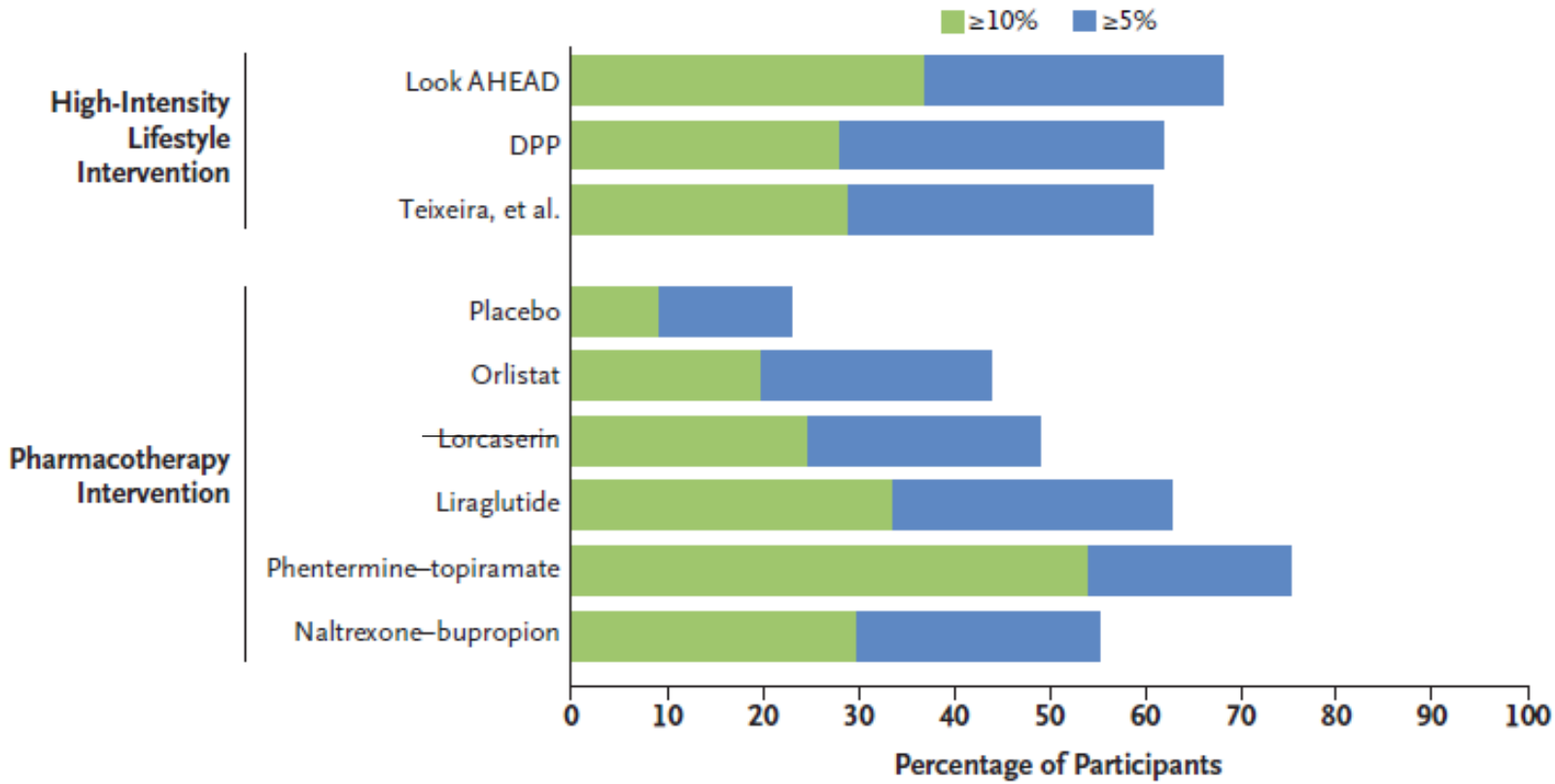


Figure 2. Weight Loss at 1 Year with High-Intensity Lifestyle Interventions or Pharmacotherapy Combined with Low-to-Moderate-Intensity Lifestyle Counseling.

Management of obesity

- Lifestyle modification
  - Diet
  - Physical activity
  - Behavioral therapy
- Pharmacotherapy
- Bariatric surgery

N Engl J Med 2017;376:254-66.

Management of obesity

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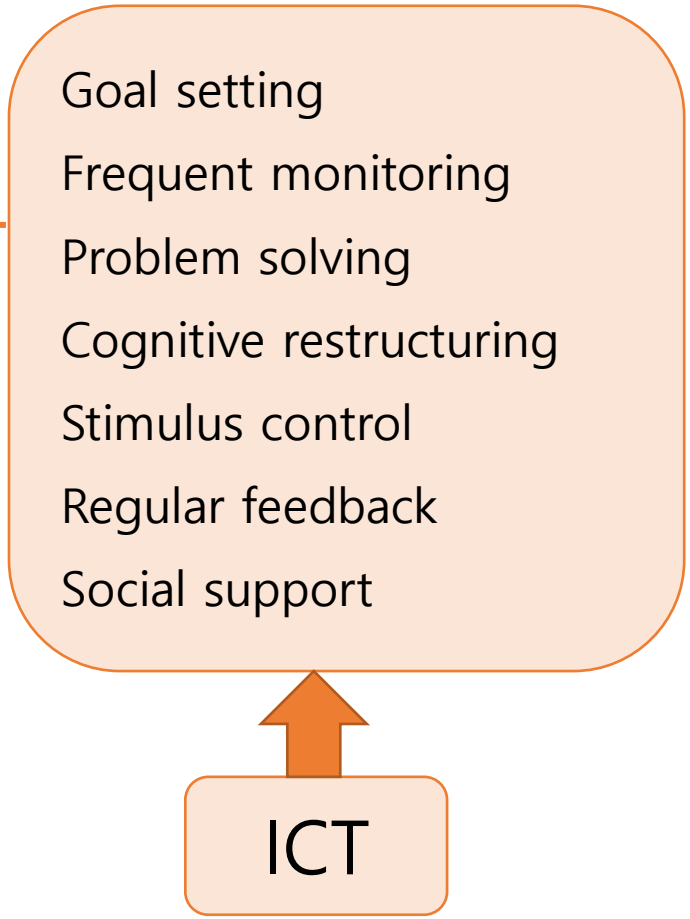

Obesity (Silver Spring) 2014; 22: Suppl 2: S41-410.

Digital delivery of behavioral intervention

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.

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Digital Health Provider Noom Wins Full CDC Recognition for Mobile, Online Applications

Apr 12, 2017
Mary Caffrey

Full recognition is key as the provider of the Diabetes Prevention Program awaits rules for Medicare reimbursement. CMS will offer the program to Medicare beneficiaries in 2018.

Noom Inc, a New York City-based digital behavioral health company, on Tuesday received full CDC recognition for its mobile and online applications of the Diabetes Prevention Program (DPP), becoming the first virtual provider to achieve this status.

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**

- 1 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 diet, activity, weight
- personalized health coaching, online social network

- In a 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

BMJ Open Diab Res Care 2017;5:e000422

Contents

Definition

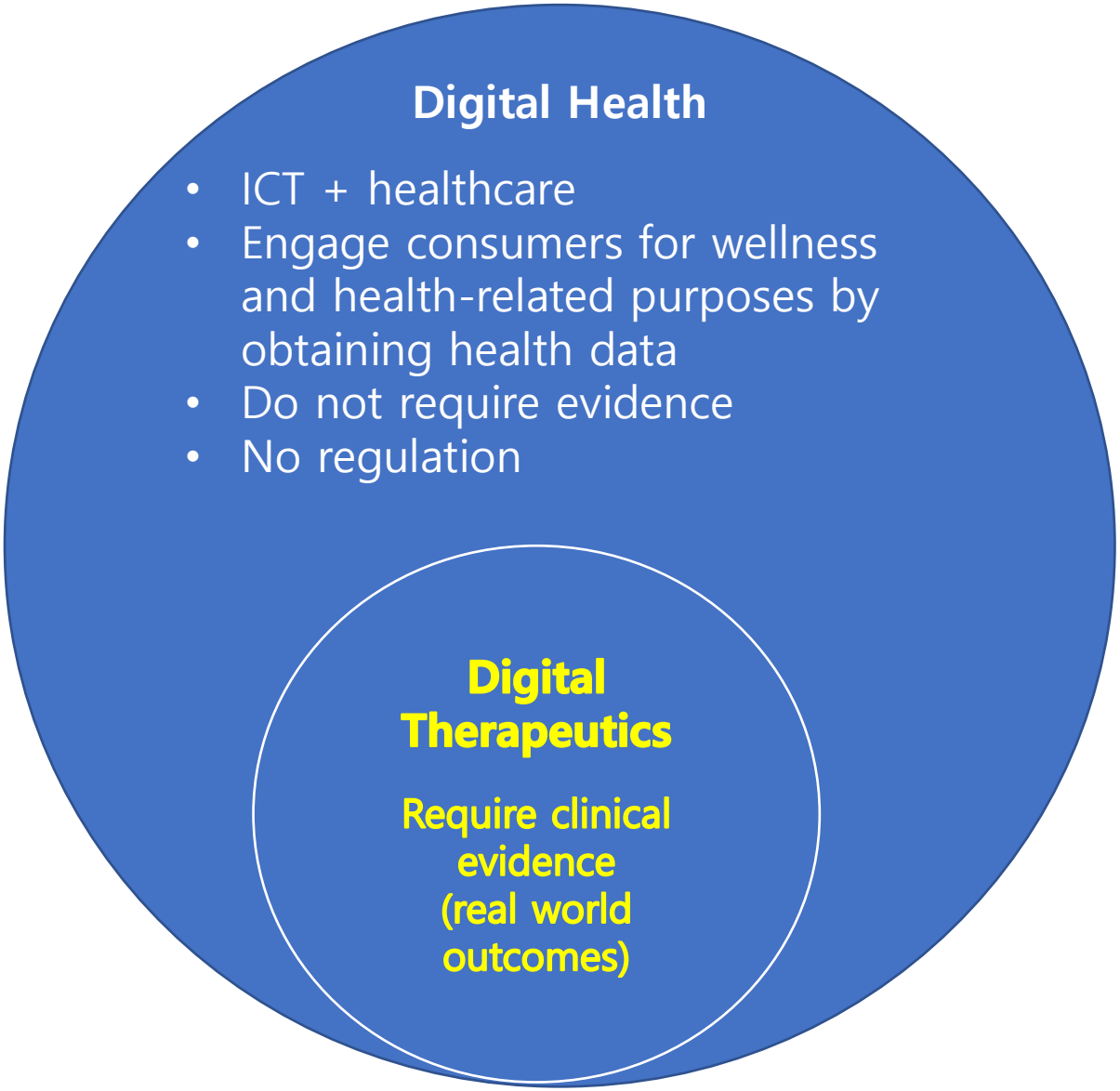
Digital therapeutics (DTx)

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/



J Med Internet Res 2005;7:e9.

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

Major DTx products and companies.

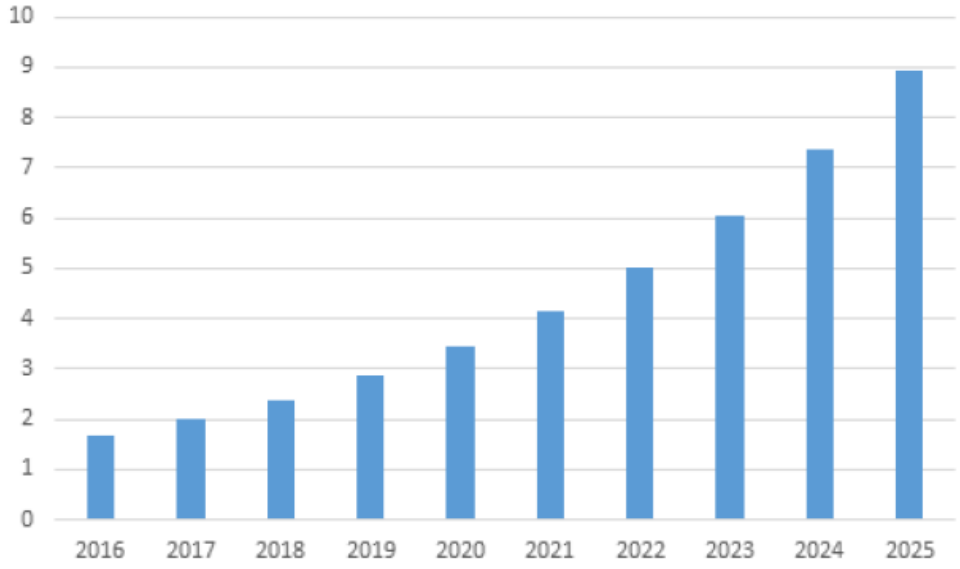
Classification	Product	Company	Device classification	Therapeutic area	Approval status	Partnership
Prescription DTx	BlueStar [24–28]	WellDoc	Mobile app/web portal connected to blood glucose meter - infusion pump accessories (MRZ); Medical computers and software (LNX)	Type 1 and type 2 diabetes	FDA-510(k)	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 (PTSD)	FDA-510(k)	Silicon Valley TMS
	Digihaler [46]		management - digital inhaler with built-in sensors that connects to a companion mobile app			
	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

Patent applications for digital therapeutics in US

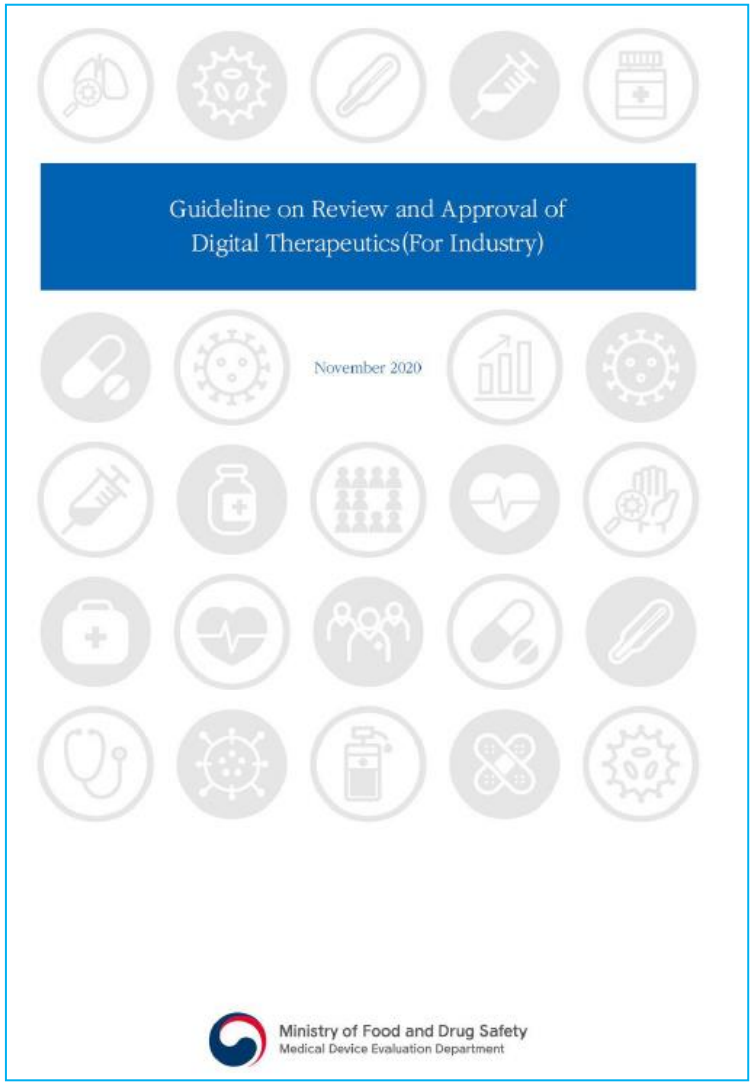
Clinical trials of digital therapeutics (ClinicalTrial.gov)



Digital therapeutics global market size (Billion dollars)

KISTEP 한국과학기술기획평가원 Korea Institute of S&T Evaluation and Planning

Korea Institute of S&T Evaluation and Planning, 2020



South Korea approves its first digital therapeutic

An app to treat insomnia has become the first digital therapeutics (DTx) to be approved for marketing by the Ministry of Food and Drug Safety (MFDS) in South Korea.

The software as a medical device (SaMD) app – Aimmed's Sommz – relies on a cognitive behavioural therapy (CBT) approach that has been put through its paces in clinical trials conducted within South Korea.

pharmaphorum
bringing healthcare together

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

Types of interventions using technologies

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



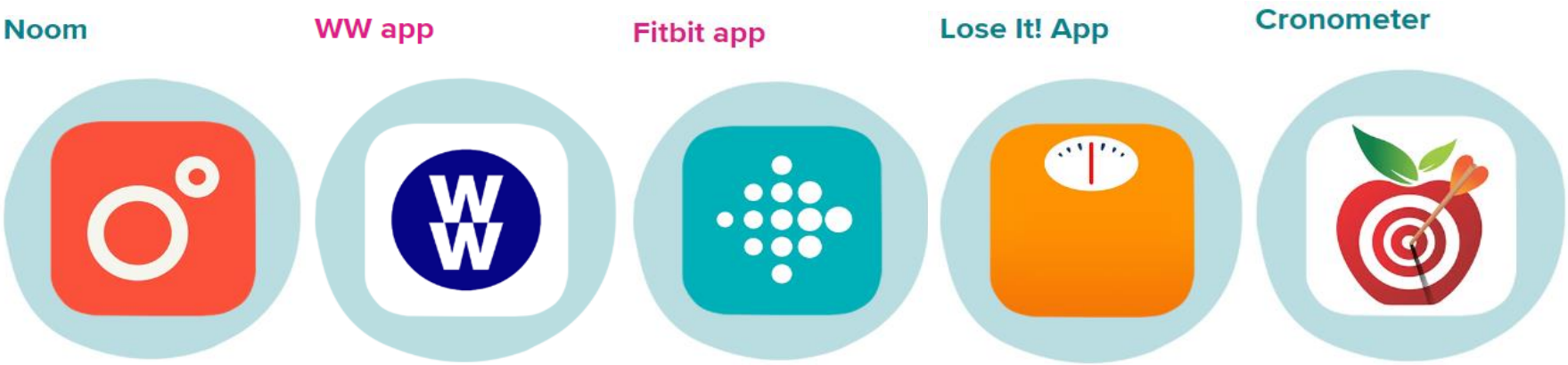


Mobile application

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

Common features

- Food and exercise logging
- Body weight monitoring

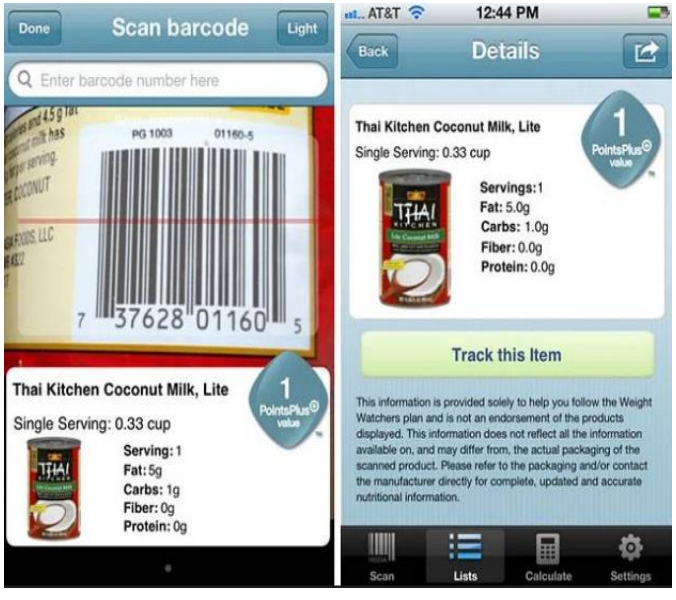


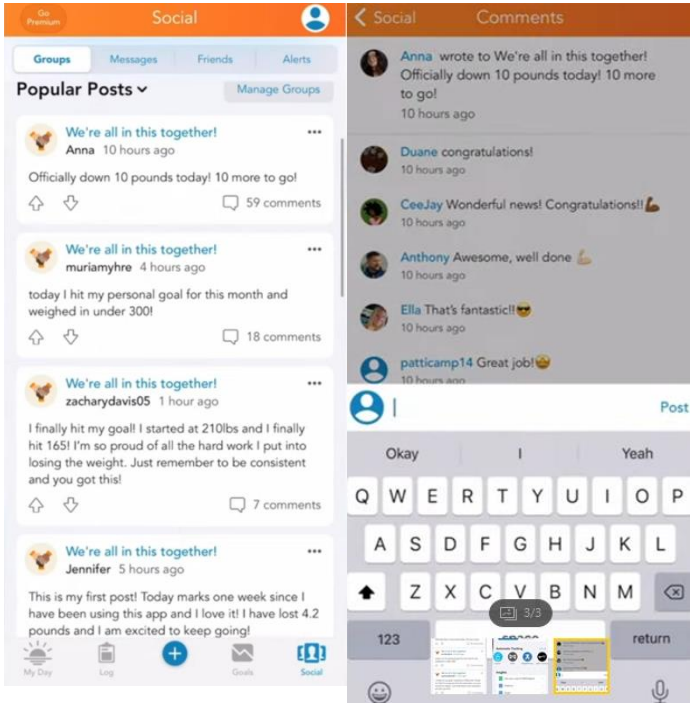
JMIR mhealth uhealth. 2020;8(7):e17039

Mobile application

Extra features

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





Popular apps

	Best for	Free version	Monthly subscription
Cronometer	Nutrient tracking	Yes	$8.99 (optional)
Diabetes Tracker	Diabetes management	Yes	$9 (optional)
FatSecret	Sharing data with a healthcare professional	Yes	$6.49 (optional)
Fooducate	Grocery shopping	Yes	in-app purchases of $9.99–$89.99
Lose It!	Calorie tracking	Yes	$9.99 (optional)
MyFitnessPal	Calorie tracking	Yes	$9.99 (optional)
Noom	1-on-1 coaching	No	$59
PlateJoy	Meal planning	No	$12.99
Strides	Goal setting and habit tracking	Yes	in-app purchases of $4.99–$39.99
WeightWatchers	Community-supported weight loss	No	$23–$50

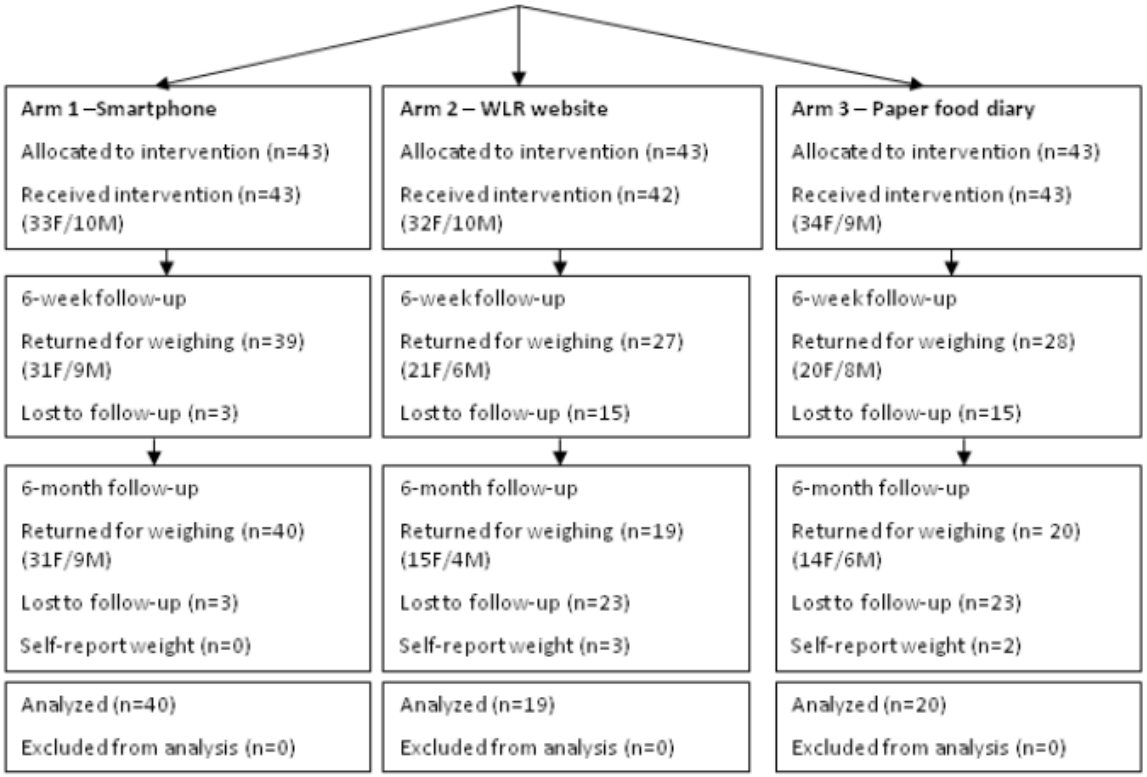
https://www.healthline.com/nutrition/10-best-weight-loss-apps#our-picks

JOURNAL OF MEDICAL INTERNET RESEARCH

Original Paper

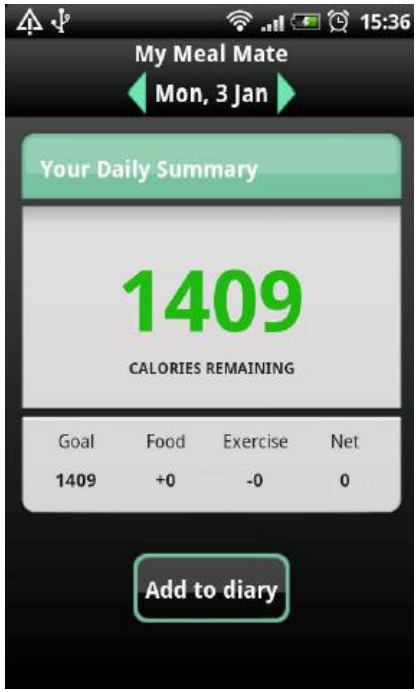
Adherence to a Smartphone Application for Weight Loss Compared to Website and Paper Diary: Pilot Randomized Controlled Trial

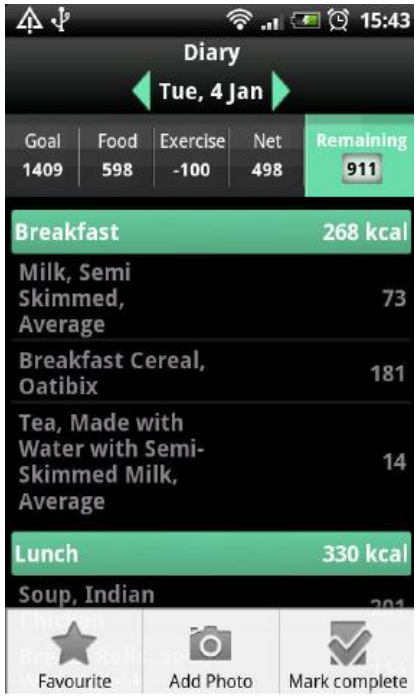
Michelle Clare Carter, MA, RD; Victoria Jane Burley, MSc, PhD; Camilla Nykjaer, MSc; Janet Elizabeth Cade, MSc, PhD



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

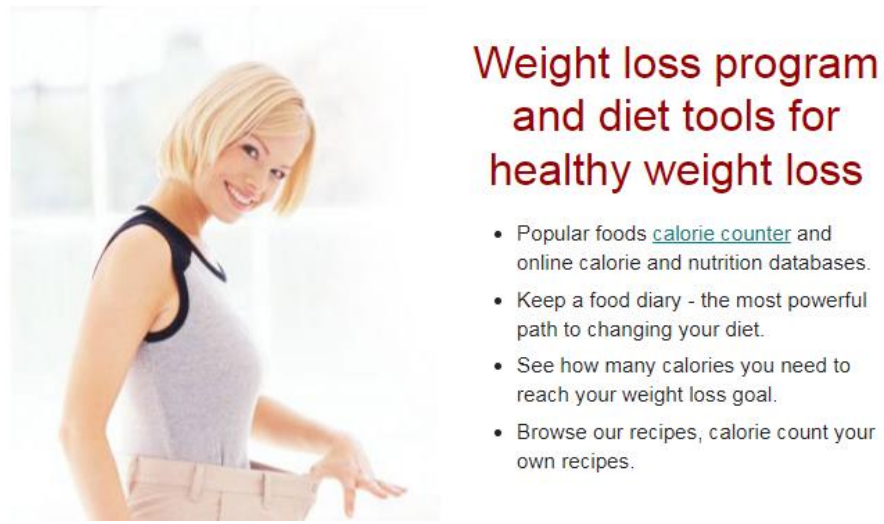
J Med Internet Res. 2013;15(4):e2283





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

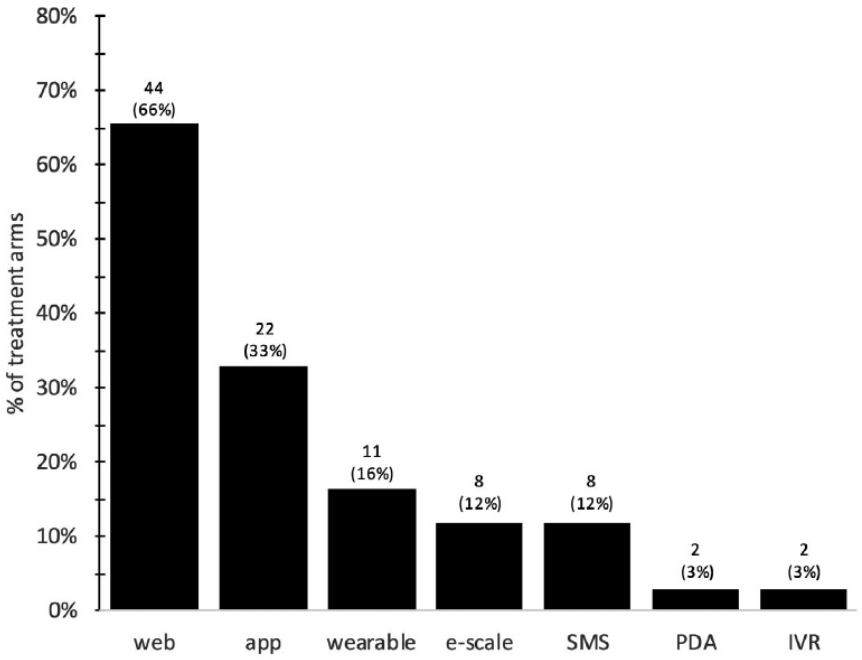
Review
CLINICAL TRIALS AND INVESTIGATIONS

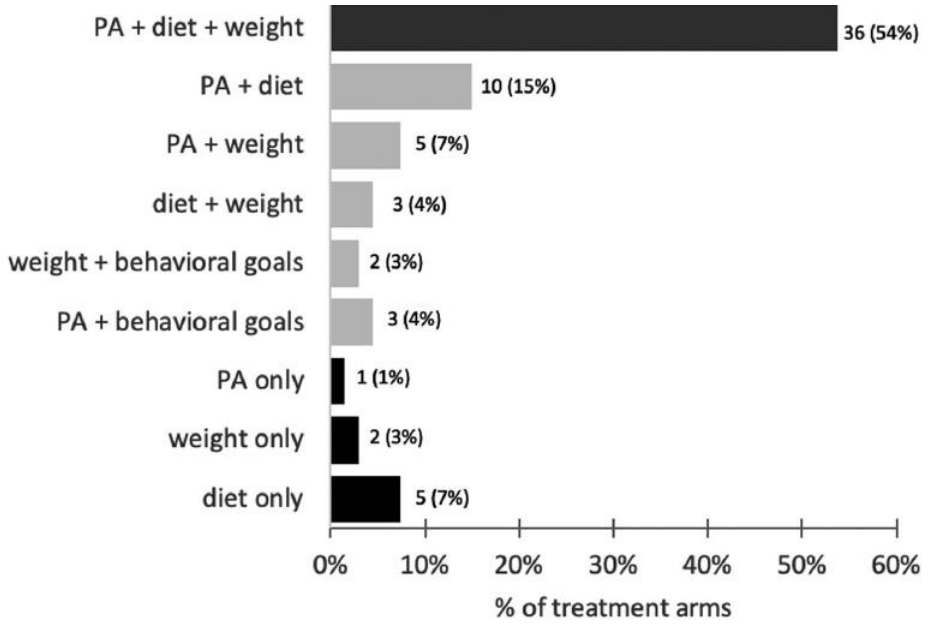
Obesity

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.

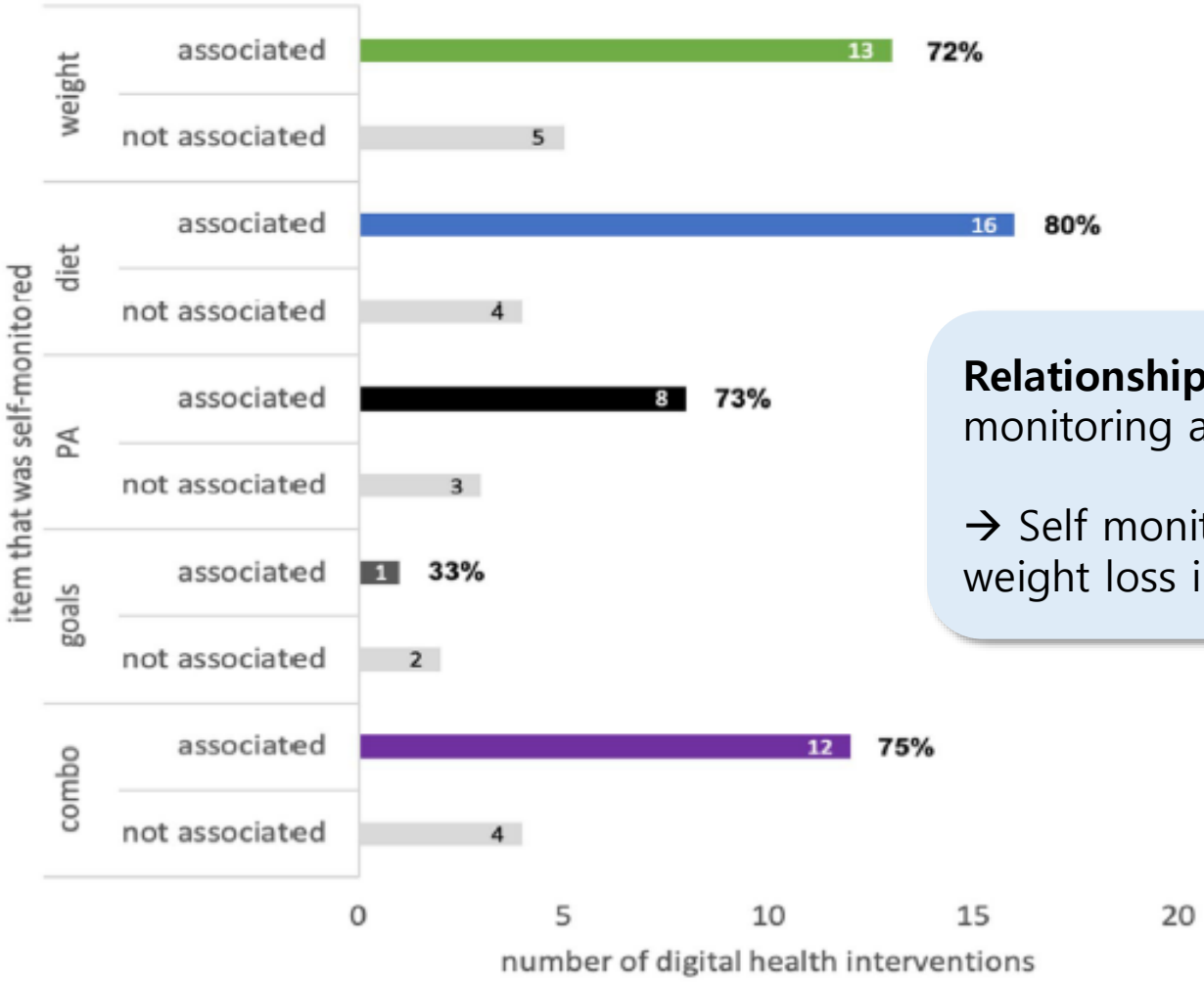


Figure 5 Relationship between digital self-monitoring and weight loss, by behavior type. Interventions that reported associations for each self-monitored item separately are represented in the figure in multiple sections rather than in the "combo" section; not all studies with digital self-monitoring 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]

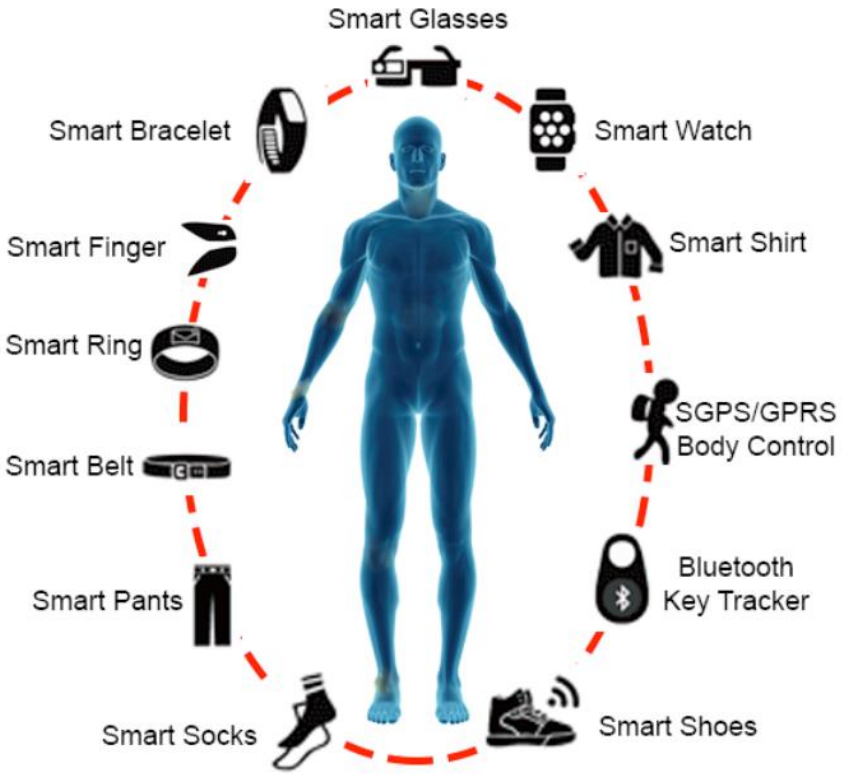
Relationship between digital self-monitoring and weight loss

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

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

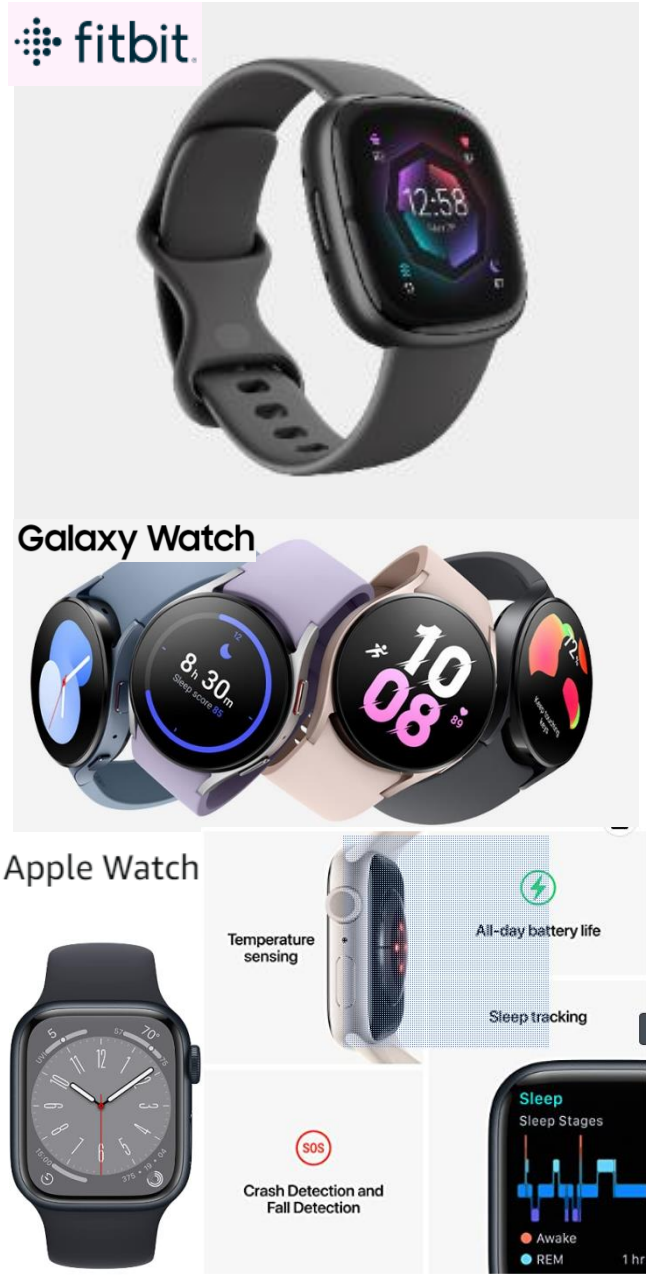
- Pedometer (step counter)
- Accelerometer
- GPS (global positioning system)
- PPG (photoplethysmogram) : optical sensor to measure HR, HRV, SpO2

Ieee Access 2018, 6, 13129-13141.

Wearable devices

Common features (Monitoring)

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

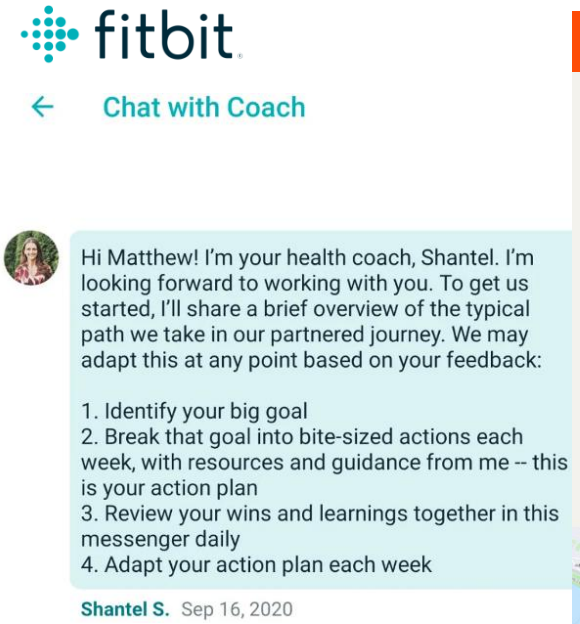


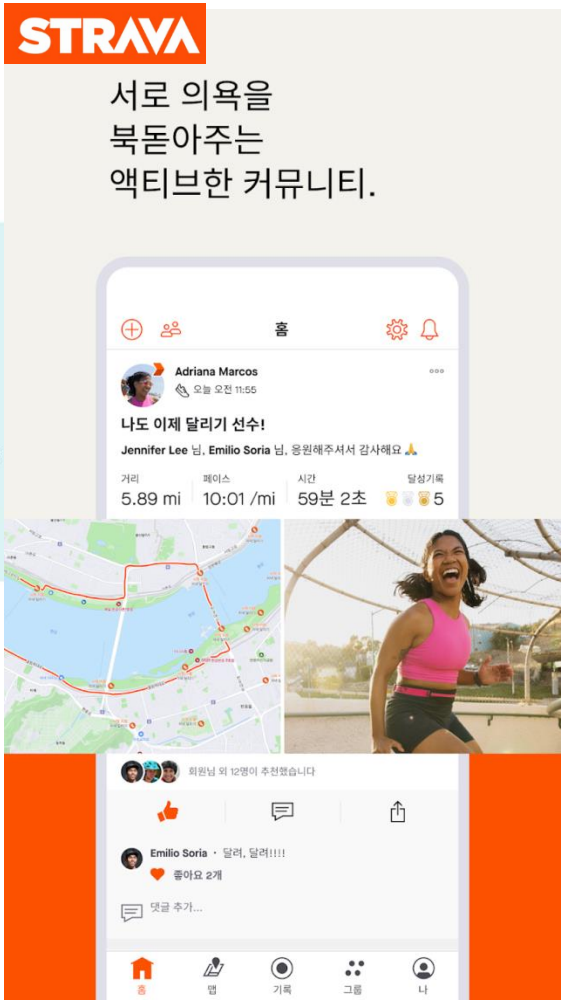
Obesity Reviews. 2019;20:1485–1493.

Wearable devices

Extra features

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





Obesity Reviews. 2019;20:1485–1493.

Lancet Digit Health 2022;
4: e615–26

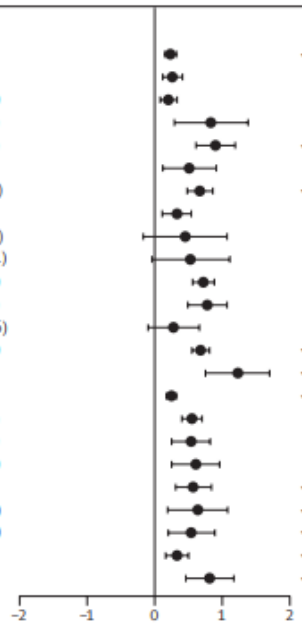
Effectiveness of wearable activity trackers to increase physical activity and improve health: a systematic review of systematic reviews and meta-analyses

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 environmental situation (ex. food cue)
- Body image : motivation for weight loss through virtual ideal self
- Physical activity : VR exergame (games requiring bodily movement) in adolescents

Virtual Reality in Eating Disorders and Obesity

Posted On: 4th June 2014

➢ By Giuseppe Riva & Enrico Molinari

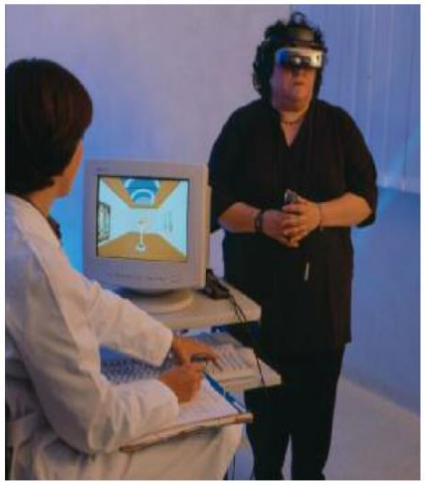


Figure 1: A patient undergoes experiential cognitive therapy

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

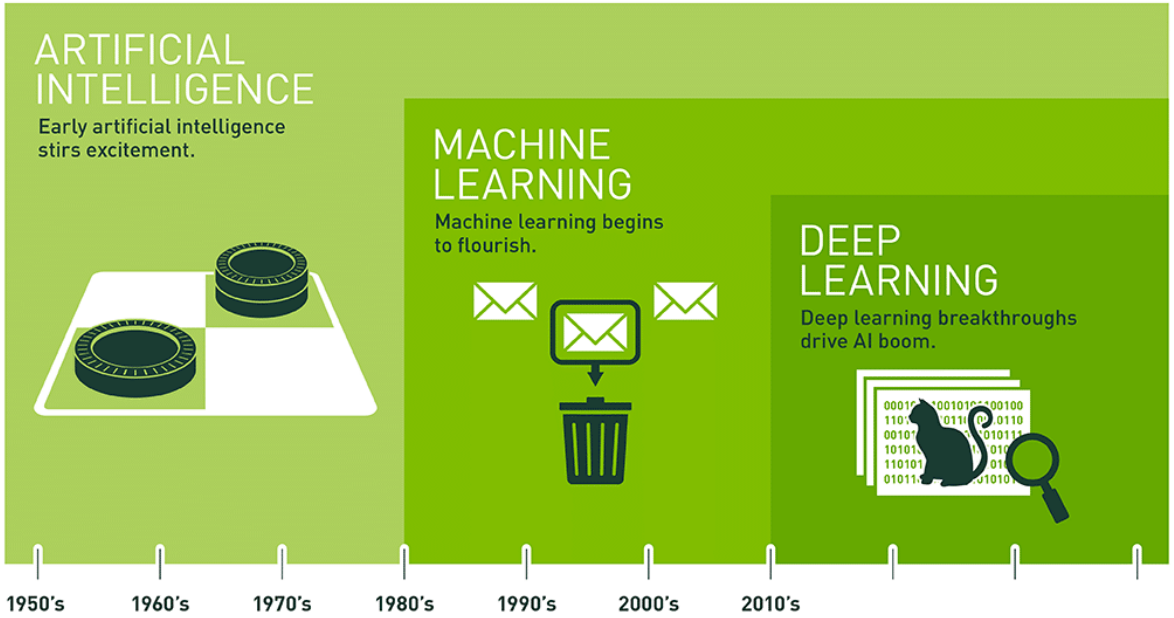
Published Online: 16 Feb 2016 | https://doi.org/10.1089/cyber.2015.0203

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

Newer technologies

TBM

ORIGINAL RESEARCH

Feasibility of pediatric obesity and prediabetes treatment support through Tess, the AI behavioral coaching chatbot

Taylor N. Stephens,[1] Angela Joerin,[2] Michiel Rauws,[2] Lloyd N. Werk[3,4]

Participants: Adolescent patients who were enrolled in a weight management program (n = 23; Mean age = 15.20 years)

Tess: AI behavioral coaching chatbot
→ To promote adherence, behavior change, overall wellness

Results: Reported experiencing positive progress toward goals (81% of the time), usefulness ratings (96% of the time) → **potential to improve the quality of care** in the existing weight management program

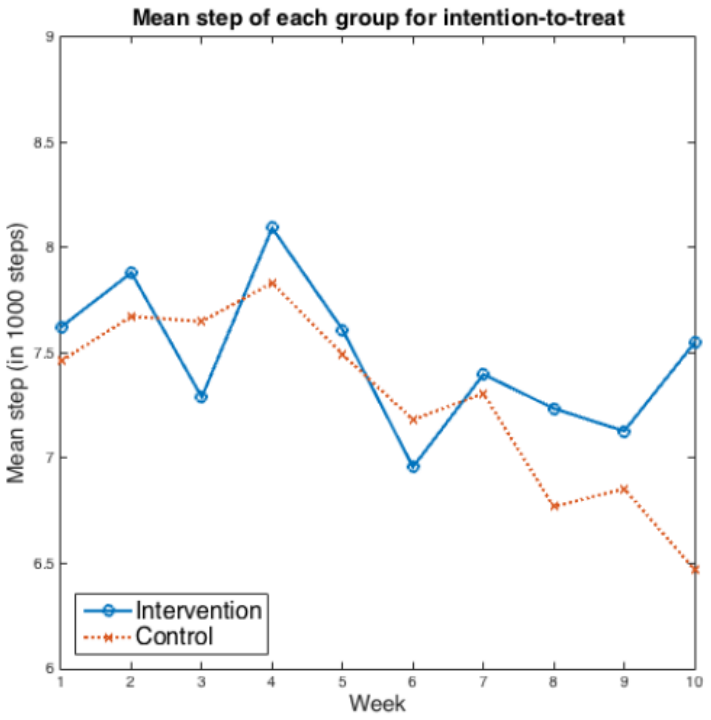
Newer technologies

JMIR MHEALTH AND UHEALTH Zhou et al

Original Paper

Evaluating Machine Learning–Based Automated Personalized Daily Step Goals Delivered Through a Mobile Phone App: Randomized Controlled Trial

Mo Zhou[1], MS; Yoshimi Fukuoka[2,3], RN, PhD, FAAN; Yonatan Mintz[1], MS; Ken Goldberg[1,4], PhD; Philip Kaminsky[1], PhD; Elena Flowers[3,5], RN, PhD; Anil Aswani[1], PhD



10-week RCT, **64 participants**

After 1-week of run-in period,
Intervention group (CalFit app): fully automated adaptively personalized daily step goals
Control group: constant step goals of 10,000 steps per day

Results: intervention group (n=34) had a decrease in mean (SD) daily step count of 390 (490) steps between run-in and 10 weeks, compared with a decrease of 1350 (420) steps among control participants (n=30; P=.03).

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

Contents

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.

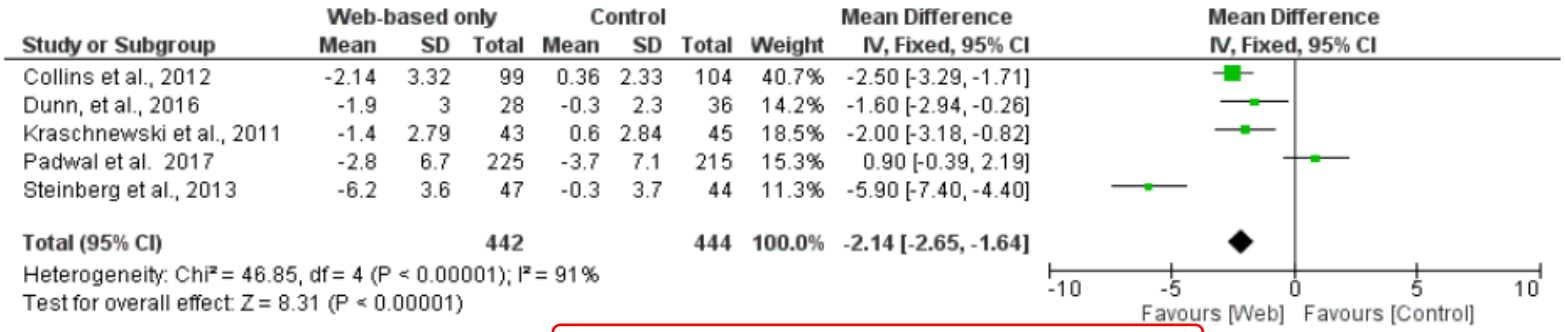


Figure 7. Meta-analysis results for mean weight change (kg) in Web-based-only versus offline interventions for studies with <6 months follow-up duration. df: degrees of freedom; IV: interval variable; random: random effects model.

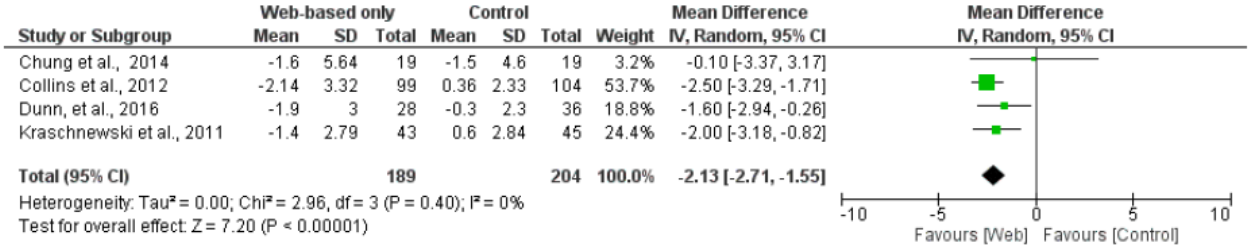
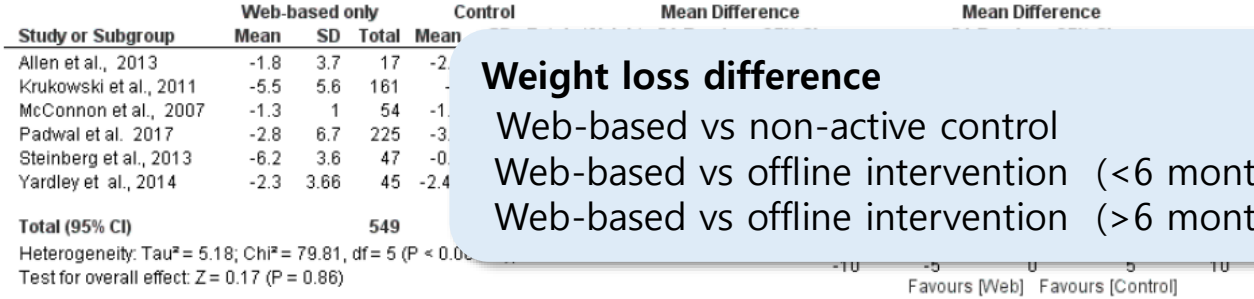


Figure 8. Meta-analysis results for mean weight change (kg) in Web-based-only versus offline interventions for studies with ≥6 months follow-up duration. df: degrees of freedom; IV: interval variable; random: random effects model.



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 intervention

- 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 + conventional intervention

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

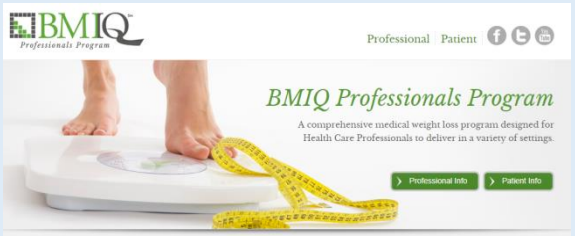
Question Does a combined intervention, including an online weight management program integrated with population health management (additional support and outreach from nonclinical staff), increase weight loss at 12 months among primary care patients compared with the online program only and usual care?

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

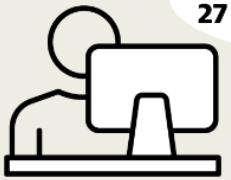
Mean (SD): 22.12 (4.85) y

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

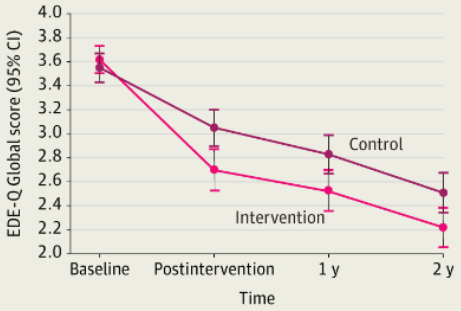
Referral to on-campus counseling center (305 women)

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
Baseline: 3.62
Postintervention: 2.70
1 y: 2.55
2 y: 2.22

EDE-Q Mean Score
Baseline: 3.55
Postintervention: 3.05
1 y: 2.83
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

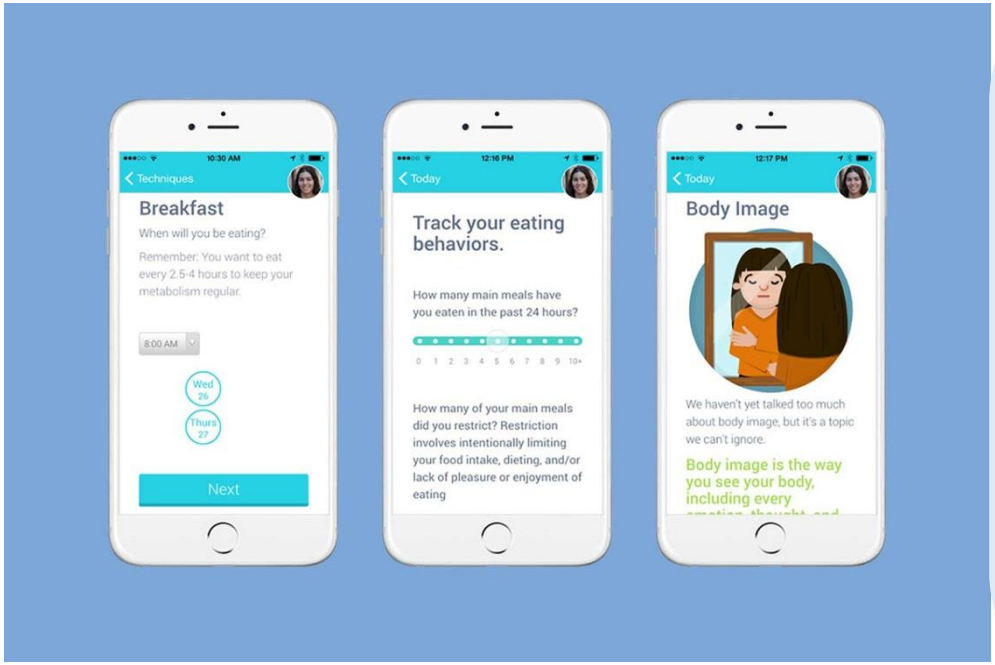
Student Bodies–Eating Disorders (SB-ED)

- 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)

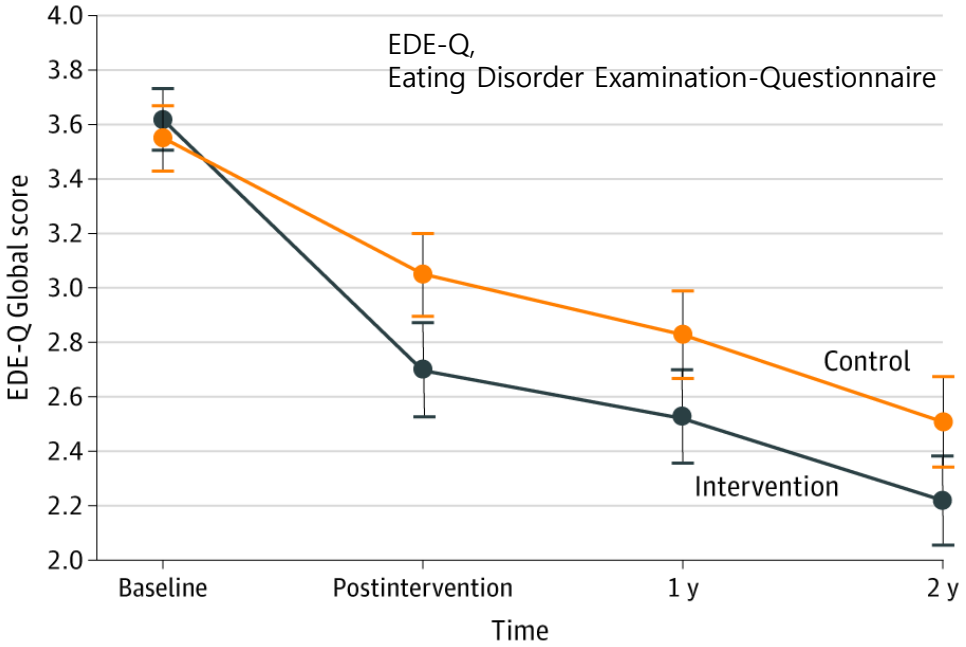
Improving body image

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.

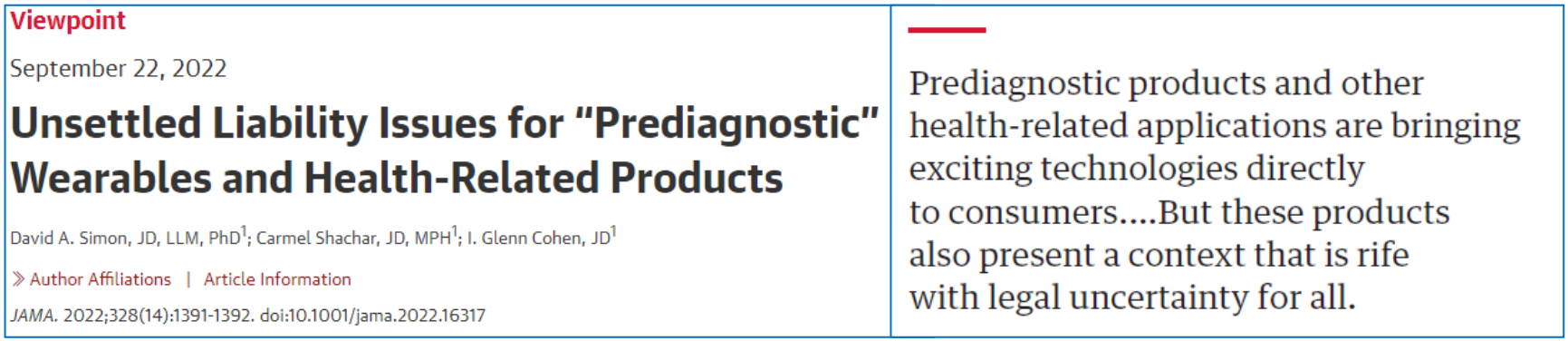
- However, there are limitations
  - **Continuity** of participation
  - **Effect size** is small
  - **Comparative benefit** to face-to-face treatment is **controversial**

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

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

Contents

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

Global Digital Health Partnership

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.

Our Work

The GDHP has five work streams, selected by GDHP members, that work together to develop and implement projects that dynamically impact digital health globally as well as for the GDHP members.

Cyber Security

Creating strategies to secure healthcare devices, data, systems, and networks

Learn More →

Interoperability

Promoting data sharing between providers, patients, and caregivers

Learn More →

Evidence & Evaluation

Sharing methods, best practices, and examples of digital health evaluation frameworks

Learn More →

Clinical & Consumer Engagement

Building digital health literacy across global healthcare

Learn More →

Policy Environments

Promoting smart policymaking to foster effective, secure digital health technology use

Learn More →

https://gdhp.health/

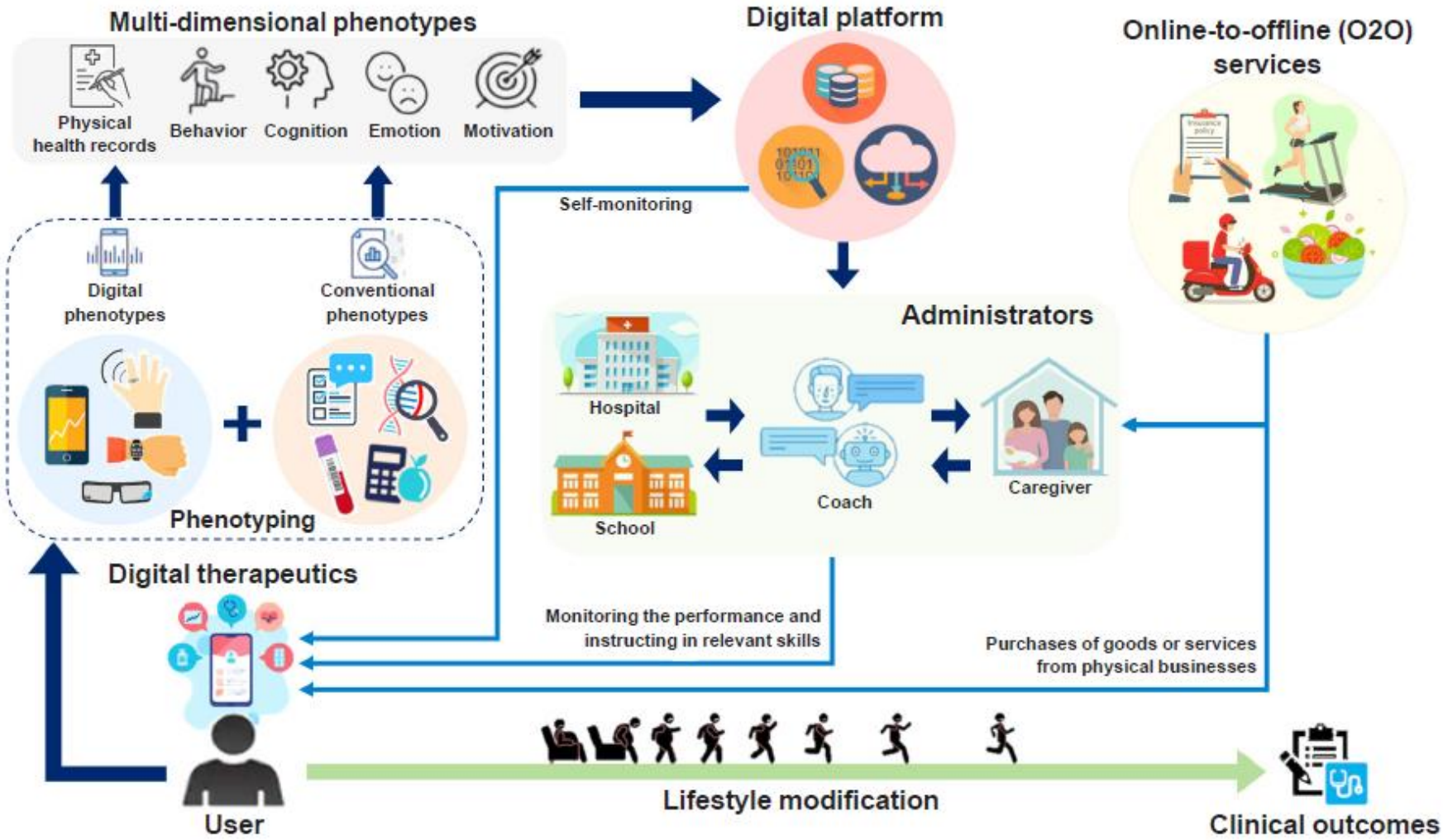


Fig. 3. Future perspectives for the ecological environment of digital therapeutics.

Take home message

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

Clinical evidence
- Potential as adjuncts to conventional interventions 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

Thank you