

Trial	Random sequence generation	Allocation concealment	Incomplete outcome data	Selective reporting	Other biases
Abroms et al [53]	<b>High risk</b>  Participants were previously enrolled in a similar study.  <i>“Pregnant women enrolled in Text4baby”</i>	<b>High risk</b>  Within group study	<b>High risk</b>  Small sample size and response rate dropped by 35% 4< follow up.  <i>“Of the 20 enrolled, 16 completed the 2-week follow-up survey (80% response rate), and 13 completed the 4-week follow up survey (65% response rate).”</i>	<b>Low risk</b>  It seems that all outcomes were reported.	<b>Low risk</b>  None detected
Abroms, Boal, Simmens, Mendel & Windsor [54]	<b>Low risk</b>  Participants randomized to control and intervention groups  <i>“Participants</i>	<b>Unclear</b>  Not reported within Methods section.	<b>Low risk</b>  High engagement with follow up data collection up to 6 months.	<b>Low risk</b>  It seems that all outcomes were reported.	<b>High risk</b>  Paid study  <i>“Participant s received a \$15 Amazon gift card for each</i>

(n=503) were recruited on the Internet and randomized to receive Text2Quit or self-help material”

“Follow-up rates for the 1-, 3-, and 6-month surveys were 85.7%, 82.9%, and 75.7% respectively.”

completed survey and a \$25 Amazon gift card for providing a saliva sample.”

Buller, Borland, Bettinghaus & Zimmerman [58]

**Low risk**      **Unclear**      **Low risk**      **Low risk**      **Low risk**

Participants randomized to control and intervention groups

Not reported.

Good engagement with intervention.

Study appeared to report results well.

None detected

“Young adult smokers 18-30 years old (n = 102) participated in a randomized pretest-posttest trial.”

“Overall, 60% of smokers used mobile services.... and 75% evaluated REQ-Mobile as user-friendly”

“REQ-Mobile was feasible for delivering cessation support but appeared to not move smokers to quit as quickly as text messaging.”

Choi, Lee, Vittinghoff & Fukuoka [59]

**Low risk**      **Low risk**      **Low risk**      **Low risk**      **Low risk**

Randomization was computer generated.

Allocation was adequately concealed.

High engagement and follow up rates.

All outcomes were reported, including the insignificant,

None detected

“Randomization”      “Allocation”

was computer-generated and stratified by body mass index category based on self-reported pre-pregnancy weight and height..."

was concealed in opaque envelopes."

"Twenty-nine women (96.7%) completed the 12-week visit: 14 intervention and 15 control participants."

alongside the possibility of adverse events.

"Although we did not find a statistically significant between-group difference in step in the increases in step counts, we did find some evidence for beneficial intervention effects on selected barriers to exercise as well as pregnancy symptoms....T here were no serious adverse events (hospitalization or emergency

visits)  
 associated  
 with the  
 intervention.”

Glynn et al  
 [60]

<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
Randomization was computer generated.	Allocation was adequately concealed.	High retention rate over the 8 week study.	Only one participant didn't reach completion.	All outcomes stated were reported.	None detected
“Randomisation occurred using random permuted blocks to ensure there were similar numbers of participants in the intervention and control groups.”	“An independent investigator was responsible for generating the allocation sequence using the Research Randomizer computer software program.... The same independent investigator was responsible for assigning participants to the intervention				

*and control groups after being called at a central site.”*

Harries et al  
[61]

**Unclear**

Not reported

**Unclear**

Not reported

**High risk**

Participant’s usage of the app dropped.

“As illustrated in Figure 5, the app was opened most often in the first few days of the study, with usage thereafter declining – first rapidly and then more gently.”

**Low risk**

All outcomes reported

**High risk**

Most participants male.

“Although the study could have been conducted with either men or women, it was decided to focus on men because of the need for the study phones to be carried in trouser pockets and the likelihood that women would find it more

*difficult to  
comply with  
this  
requirement  
.”*

Hertzberg et al [62]	<b>Low risk</b>	<b>Unclear</b>	<b>Low risk</b>	<b>Low risk</b>	<b>High risk</b>
	Participants were randomized.  “22 (participants) were randomized to receive either mCM or to a yoked condition”	Not reported	High retention  “Two participants (one in the mCM condition and one in the yoked condition) withdrew prior to the quit date.”	Reported all outcomes and insignificant results.  “logistic regression failed to indicate a significant condition effect for end-of-treatment abstinence.”	Paid study
Lee, Koopmeiners, Rhee, Raveis, Jasjit & Ahluwalia [55]	<b>High risk</b>	<b>High risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
	Within group study	Within group study	High retention rate	Reported all outcomes	None detected
McGillicuddy et al [63]	<b>Low risk</b>	<b>Unclear</b>	<b>Low risk</b>	<b>Low risk</b>	<b>High risk</b>
	Participants were adequately randomised.	Allocation protocol not reported.	Small sample size but high retention rate in second	Reported all outcomes	First study of its kind.  “To our

*“20 subjects were randomly assigned to either the mHealth intervention or to standard care.”*

*phase.  
“Of the 21 subjects randomized, 1 was withdrawn for scheduling conflicts; the remainder completed the second phase of the study.”*

*knowledge, this is the first randomized controlled trial in kidney transplant recipients that has simultaneously examined the use of real time medication reminder and monitoring devices along with wireless measurement of relevant physiological indices to facilitate timely reinforcement based on adherence levels.”*

Participants adequately randomised.	Adequate allocation concealing.	No participants were lost at the follow up stage.	All outcomes were reported.	None detected
<i>"To evaluate ALICE we opted for a single-blind experimental design with 2 groups (control and experimental) (NCT02071498). Patients were randomly assigned to the control or experimental group."</i>	<i>"To maintain the blinding and be able to link the pre and post measurements, patients were assigned codes based on their date of birth and initials."</i>			

Park, Howie-Esquivel, Chung & Dracup [56]	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
	Adequate random sequence generation	Adequate allocation concealment	Only lost 6 participants in follow ups.	All data reported adequately	None detected
	<i>"Group assignment was generated by random allocation sequence using blocks of six that</i>	<i>"The PI assigned patients to their group by distributing envelopes in consecutive, numbered</i>	Intervention a (n=2) Intervention b (n=2) Control group (n=2)		



Partridge et al [78]	<p>was prepared by order.”</p> <p>a</p> <p>biostatistician.”</p> <p><b>Low risk</b></p> <p>Independent sequence generation</p> <p>“A random sequence was generated by an independent researcher-“</p>	<p><b>Low risk</b></p> <p>Adequate allocation concealment</p> <p>“-and concealed from those responsible for enrolling participants into the intervention arm.”</p>	<p><b>Low risk</b></p> <p>No drop outs from control group and only 10 from the intervention.</p> <p>Dropped out immediately (intervention, n=2)</p> <p>Dropped out at 12 week follow up (intervention, n=8)</p>	<p><b>Low risk</b></p> <p>All outcomes reported thoroughly</p>	<p><b>High risk</b></p> <p>Focus on strengths of study and not limitations within the discussion section.</p>
Turner-McGrievy & Tate [65]	<p><b>Low risk</b></p> <p>Randomisation was computer generated</p> <p>“Participants were randomly assigned using a computerized random numbers generator-“</p>	<p><b>Unclear</b></p> <p>Not stated within the study</p>	<p><b>Low risk</b></p> <p>High retention rate</p> <p>“Participants who did not complete the study at 6 months (n = 10)”</p>	<p><b>Low risk</b></p> <p>All outcomes reported including insignificant ones.</p> <p>“The group-by-time interaction was not significant for</p>	<p><b>Low risk</b></p> <p>None detected</p>

*any of the variables. The percentage weight loss at 3 or 6 months did not differ between the groups."*

Laing et al  
[66]

**Low risk**

Independent, unbiased sequence generation

*"Our statistician used R to generate the permuted block sequence."*

**Low risk**

Adequate allocation concealment

*"We printed the sequence and placed it in opaque envelopes."*

**High risk**

High dropout rate

*"At 3 months, 26% of intervention group participants and 21% of control group participants were lost to follow-up or had withdrawn-. At 6 months, 32% of intervention group participants and 19% of control group participants were lost to*

**Low risk**

All outcomes reported

**Low risk**

None detected

*follow-up or had withdrawn."*

Arean et al [67]

**Low risk**

**Unclear**

**Low risk**

**Low risk**

**High risk**

Adequate randomisation  
  
"We randomly assigned participants to 1 of the 3 apps using a random number generator built into the eligibility survey."

Not stated within the study

Only 3 participants didn't complete

No selective reporting apparent

Gender split  
  
"The majority of the sample was female"

Kinderman et al [68]

**Low risk**

**High risk**

**High risk**

**High risk**

**High risk**

Within group study

Within group study

Low usage rate  
  
"majority of participants only used the app one or two times: 65% (186/285) used it once with 17% (49/285) returning to use it a second

Positive generalisation of results from a relatively small sample size.  
  
"although the absolute uptake of the Catch It app was low (7%

Low uptake  
  
"absolute uptake was low and most users made few entries"

time. This figure dropped to 7% (21/285) for three entries... with only one participant using the app more than 13 times.”

of the available population), this would, for the wider general population, represent a highly cost-effective intervention.”

Kuhn et al [69]	<b>Low risk</b>	<b>High risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
	Within group study	Within group study	Data from all participants analysed	All relevant data reported	None detected
Proudfoot et al [70]	<b>Low risk</b>	<b>Unclear</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
	Randomisation was carried out by an independent person.	Allocation to group was mentioned but not the concealment.	High retention rates	Both primary and secondary outcomes were reported	None detected
	“A research assistant not involved in the RCT randomised participants after baseline using computerised random	“Allocation was either to the myCompass, AC or WL condition.”			

numbers.”

Pramana, Parmanto, Kendall & Silk [71]	<b>Low risk</b> Within group study	<b>High risk</b> Within group study	<b>Low risk</b> High compliance rate  “Figure 8 suggests that patients were compliant with the protocol, completing an average of 5.36 entries out of 6.48 requests (82.8% completion rate) between each session (standard deviation=1.95).”	<b>Low risk</b> No selective reporting detected.	<b>High risk</b> The study gave the potential to earn rewards.  “Patients earn prizes for completing skills coach entries.”
Whittaker et al [57]	<b>Unclear</b> Random sequence generation was not noted in the study	<b>Low risk</b> Adequate allocation concealment  “This research was part of a	<b>High risk</b> Only a fraction of the sample viewed all of the intended messages.	<b>Low risk</b> All results were reported accordingly  “disappointingly the	<b>Low risk</b> None detected

*double-blind RCT* “29.6% (n = 123) viewing most or all of the messages” *intervention group participants were no more likely than the control group participants to know where to go for help.”*

Kauer et al  
[72]

<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
Adequate random sequence generation.	Adequate allocation concealment.	Accounted for missing participants	No selective reporting detected	None detected	
“This was a multicenter, multiregional, stratified, single-blind, attention-controlled study with balanced (1:1) individual randomization”	“This process was blinded; the intervention and comparison program could not be differentiated when downloading the program.”	“we included all 114 participants (68 in the intervention group and 46 in the comparison group) in analyses using the routines for missing data in the maximum likelihood estimation.”			

Watts et al

**Low risk**      **Low risk**      **High risk**      **Low risk**      **Low risk**

[27]

Get Happy programme	Independent persons carried out the randomisation process.  "were randomised via a true randomisation process generated by a team member not involved in the study"	Adequate allocation concealment.  "Concealment of allocation was maintained until the applicant met all inclusion criteria and an offer of participation made."	Low adherence rates. If engagement was low, data could be skewed.  "8.6% (3/35) completed only the first lesson, 2.9% (1/35) completed two lessons, 2.9% (1/35) completed 3 lessons, 5.7% (2/35) completed 4 lessons, 11.4% (4/35) completed 5 lessons and 68.6% (24/35) of participants completed all six lessons."	All outcomes were thoroughly measured	None detected
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Ben-Zeev et al  
[73]

Within group study	<b>Low risk</b>	<b>High risk</b>	<b>Low risk</b>	<b>Low risk</b>	<b>Low risk</b>
	Within group study	Within group study	High retention rate and data collection.	No selective reporting detected	None detected

*“One participant dropped out of the study after losing 2 smartphones in the first week.”*

Torous et al  
[74]

**Low risk**

**High risk**

**Low risk**

**Low risk**

**Low risk**

Within group study

Within group study

High retention rate

No selective reporting detected

None detected

*“Out of a total of 14 patients who were offered the opportunity to participate, 13 (93%) enrolled in the study.”*

Hidalgo-Mazzei et al  
[75]

**Low risk**

**Low risk**

**Low risk**

**Low risk**

**Low risk**

Adequate random sequence generation

Excellent allocation concealment

No incomplete outcome data reported

No selective reporting detected

None detected

*“5 digits random identification number (IDN)*

*“an independent researcher... randomize the*



sample to the intervention group or to the control group” will be generated for all the participants throughout all the phases of the study. The cross-reference of this identification number and the patient identity will be encrypted and stored in a database file. Those patients using the smartphone application will be identified only by the IDN, which will be also the username to access the application.”

Pham, Khatib, Stansfeld, Fox & Green [76]	<b>High risk</b> Unblinded RCT	<b>Unclear/ High risk</b> Allocation	<b>High risk</b> Initial participants	<b>Low risk</b> No selective reporting	<b>Low risk</b> None detected
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“unblinded, concealment Intervention detected  
 Web-based, was not n=31  
 parallel-group mentioned in Control group  
 RCT focusing on the study but n=32  
 feasibility, due to the 4< weeks  
 clinical efficacy, study being (Post  
 and design proof unblended withdrawals)  
 of concept.” high is Over 4 weeks  
 assumed.

Intervention  
 n=17  
 Control group  
 n=25

Even after the  
 withdrawals  
 the initial  
 number of  
 participants  
 was included  
 in the  
 analyses.

Ly, Asplund &  
 Andersson

[77]

**Low risk**

Unbiased  
 persons carried  
 out the  
 randomisation.  
 “participants  
 were allocated  
 using an online  
 randomization

**Unclear**

Allocation  
 concealment  
 was not noted  
 within the  
 study

**Low risk**

High retention  
 “Of the 74  
 participants  
 randomized,  
 one  
 participant  
 decided not to  
 participate in

**Low risk**

Reported all  
 outcome  
 measures and  
 were impartial  
 when  
 reporting both  
 strengths and  
 limitations of  
 the study

**High risk**

First study of  
 its kind.  
 “First RCT  
 for stress  
 manage-  
 ment in  
 organization  
 al context

<i>tool, handled by</i>	<i>the study. Five</i>	<i>using a</i>
<i>an independent</i>	<i>out of the 73</i>	<i>smartphone</i>
<i>person who was</i>	<i>participants</i>	<i>app.”</i>
<i>separate from</i>	<i>(6.8%) did not</i>	
<i>the staff</i>	<i>provide post-</i>	
<i>conducting the</i>	<i>treatment</i>	
<i>study”</i>	<i>data”</i>	

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