

Do no harm – risk and potential benefits

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Why do we need interventions now?

WCRF/AICR Third Expert Report showed "persuasive evidence that nutritional factors, such as body fatness, as well as physical activity, reliably predict important outcomes for patients with cancer"

BUT

"The evidence that changing these factors after diagnosis will alter the clinical course of cancer is limited"





Establish the evidence

- Large scale, adequately powered trials
- Defined exposure periods
- Agreement on defined outcomes
- Not just breast cancer
- Consider cancer stage, treatment type and intensity and <u>comorbidities</u>





Achieving change

• Implementation of trials/interventions requires people affected by cancer to change their behaviour - we need:

- 1. Evidence-based components to support behaviour change
- 2. Interventions must be achievable

• What evidence do we have to draw from?





Identifying effective intervention components

- Michie's behaviour change technique taxonomy
 - Developed to build consensus for reporting behaviour change interventions
 - Enables synthesis of evidence

No.	Label	Definition	Example
1.1	Goal setting (behaviour)	Set or agree on a goal defined in terms of the behavior to be achieved Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code 1.3, Goal setting (outcome) ; if the goal defines a specific context, frequency, duration or intensity for the behavior, also code 1.4, Action planning	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines

BCT synthesis in cancer populations

J Car	ncer Surviv	(2017)	11:360-385
DOI	10.1007/s1	1764-01	16-0594-8



REVIEW

Toward the optimal strategy for sustained weight loss in overweight cancer survivors: a systematic review of the literature

Meeke Hoedjes¹ · Maartje M. van Stralen¹ · Sheena Tjon A Joe² · Matti Rookus³ · Flora van Leeuwen³ · Susan Michie⁴ · Jacob C. Seidell¹ · Ellen Kampman^{1,5}

- Goal setting (behaviour)
- Action planning
- Social support (unspecified)
- Instruction on how to perform the behaviour

Southam Sustained behaviour change



- To achieve long-term health benefits behaviour change must be sustained
- No previous reviews have synthesised evidence of behaviour change after intervention completion in cancer population
- Included 27 RCTs, 19 pooled in meta-analysis, coded BCTs



BCTs associated with effectiveness

- Action planning
- Social support (unspecified) _____ as per Hoedjes et al
- Graded tasks
- BUT other common BCTs; goal setting and instructions on how to perform behaviour commonly reported in BOTH effective and ineffective interventions
- BCTs are important but not magic bullets



Contextual factors and populations

- Less effective interventions tended to include
 - Older populations
 - Individuals with existing physical limitations (pain/fatigue)
 - Less likely to include supervised elements
 - Had fewer contacts with participants

Grimmett et al., in press



One size does not fit all

May 13, 2009

Effects of Home-Based Diet and Exercise on Functional Outcomes Among Older, Overweight Long-term Cancer Survivors RENEW: A Randomized Controlled Trial

Miriam C. Morey, PhD; Denise C. Snyder, MS, RD, CSO; Richard Sloane, MPH; et al

Article Information

JAMA. 2009;301(18):1883-1891. doi:10.1001/jama.2009.643

"Physical activity, dietary behaviours and overall quality of life increased significantly in Intervention versus Control arms, and weight loss also was greater, -2.06(-1.69, -2.43) versus -0.92(-0.51, -1.33) kg, respectively (p<0.0001)."

One size does not fit all



Original Article 🙃 Free Access

Group trajectory analysis helps to identify older cancer survivors who benefit from distance-based lifestyle interventions

Miriam C. Morey PhD, Cindy K. Blair PhD, Richard Sloane MPH, Harvey Jay Cohen MD, Denise C. Snyder MS, RD ... See all authors \checkmark

First published: 29 October 2015 | https://doi.org/10.1002/cncr.29684 | Cited by: 6



- Individuals with low baseline self-efficacy, no PA, and a Short Form 36 PF subscale score<65 did not benefit from the intervention.
- Parallels with recent review: older adults & those with pain/fatigue

Challenges of implementing interventions



- Gatekeeping by NHS staff
- Adhering to protocol

When should we be intervening?



People benefitting from existing interventions:

- Female
- Not 'old'
- High level of education
- Have few comorbidities
- Good physical function
- Already engage in some PA

We risk excluding those in most need of effective support



Are RCTs the 'best' design?

	Intervention			Control			5	Std. Mean Difference	Std. Mean Difference								
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl								
James 2015 (43)	79.2	104.5	33	133.1	225.7	36	3.3%	-0.30 [-0.77, 0.18]									
Ottenbacher 2012 (44)	107.58	125.53	171	103.63	143.05	253	9.8%	0.03 [-0.17, 0.22]	+								
O'Neill 2018 (49)	165	145	20	148	198	19	2.0%	0.10 [-0.53, 0.72]									
Galvao 2017 (53)	126.2	187.5	194	108.2	178.4	184	9.5%	0.10 [-0.10, 0.30]									
Witlox 2018 (48)	678	702.7	70	579	534.1	58	5.2%	0.16 [-0.19, 0.50]									
Rogers 2015 (53)	216	131	110	192	136	112	7.3%	0.18 [-0.08, 0.44]	+								
Hawkes 2013 (39)	85.2	181	205	54.3	120	205	9.8%	0.20 [0.01, 0.39]									
Vallance 2007 (52)	175	182	93	142	126	96	6.7%	0.21 [-0.08, 0.50]									
Sandler 2017 (47)	45.5	61.09	18	30.46	54.88	22	2.1%	0.26 [-0.37, 0.88]									
Pinto 2013 (56)	107.62	110.41	86	80.03	82.96	76	6.1%	0.28 [-0.03, 0.59]									
Lee 2018 (50)	705	324	111	613.3	321.4	112	7.3%	0.28 [0.02, 0.55]									
Kanera 2017 (54)	688.1	570.6	162	512.2	452.1	206	9.3%	0.35 [0.14, 0.55]									
Pinto 2013 (45)	148.6	209.8	20	86.6	103.4	26	2.3%	0.38 [-0.20, 0.97]									
Pinto 2015 (68)	98.4	83.2	39	63.9	82.9	37	3.5%	0.41 [-0.04, 0.87]									
Adams 2018 (42)	307.9	251.8	29	205.5	221.6	22	2.5%	0.42 [-0.14, 0.98]									
Belanger 2014 (40)	164	104.8	48	118	93.4	48	4.2%	0.46 [0.05, 0.87]									
Mutrie 2012 (55)	648	347	43	462	263	41	3.7%	0.60 [0.16, 1.03]									
Rogers 2009 (37)	174.9	104.8	20	92	94.12	19	1.9%	0.81 [0.16, 1.47]									
Pinto 2008 (46)	193.85	161.68	39	78.1	91.34	39	3.4%	0.87 [0.41, 1.34]									
Total (95% CI)			1511			1611	100.0%	0.25 [0.16, 0.35]	◆								
Heterogeneity: Tau ² = 0.01; Chi ² = 28.19, df = 18 (P = 0.06); l ² = 36%																	
Test for overall effect: Z	= 5.20 (P	< 0.0000	01)						Test for overall effect: $Z = 5.20$ (P < 0.00001) Favours intervention								

	Post-intervention			Pre-intervention			5	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Witlox 2018 (48)	678	702.7	70	879	1,108.6	119	5.5%	-0.20 [-0.50, 0.09]	_ - +
James 2015 (43)	79.2	104.5	33	84.1	95.2	55	4.7%	-0.05 [-0.48, 0.38]	
Galvao 2017 (53)	126.2	187.54	184	125.9	165.1	232	6.1%	0.00 [-0.19, 0.20]	+
O'Neill 2018 (49)	165	145	20	132	280.5	21	3.6%	0.14 [-0.47, 0.76]	
Kanera 2017 (54)	688.1	570.6	162	595.9	620.5	225	6.1%	0.15 [-0.05, 0.36]	+
Hawkes 2013 (39)	85.2	181	159	58.9	132.9	205	6.0%	0.17 [-0.04, 0.38]	
Rogers 2015 (53)	216	131	105	178	124	110	5.7%	0.30 [0.03, 0.57]	
Sandler 2017 (47)	45.5	61.09	18	29.47	41.43	22	3.5%	0.31 [-0.32, 0.93]	
Vallance 2007 (52)	175	182	93	119	163	93	5.6%	0.32 [0.03, 0.61]	
Pinto 2013 (56)	107.62	110.41	86	49.32	70.72	106	5.6%	0.64 [0.35, 0.93]	
Lee 2018 (50)	705	324	95	498.2	298.8	111	5.6%	0.66 [0.38, 0.94]	
Pinto 2013 (45)	148.6	209.8	19	37.6	72.5	20	3.4%	0.70 [0.05, 1.35]	
Demark-W 2012 (38)	100.9	129.38	243	33.3	51.8	319	6.2%	0.72 [0.55, 0.89]	
Rogers 2009 (37)	174.9	97.38	20	96.2	99.19	21	3.5%	0.79 [0.15, 1.42]	
Belanger 2014 (40)	164	104	48	86	76	48	4.8%	0.85 [0.43, 1.27]	
Pinto 2008 (46)	193.85	161.68	39	81.56	94.8	43	4.5%	0.85 [0.40, 1.30]	
Mutrie 2012 (55)	648	347	43	367	306	96	5.0%	0.88 [0.50, 1.25]	
Ottenbacher 2012 (44)	107.58	125.53	171	23.5	40.39	171	6.0%	0.90 [0.68, 1.12]	
Adams 2018 (42)	307.9	251.8	29	124.7	113.3	35	4.1%	0.96 [0.44, 1.48]	
Pinto 2015 (68)	98.4	83.2	36	31.8	33.9	39	4.3%	1.05 [0.57, 1.54]	
Total (95% CI)			1673			2091	100.0%	0.49 [0.32, 0.66]	•
Heterogeneity: Tau ² = 0.	12; Chi² =	114.45,	df = 19	(P < 0.0	00001); l²	= 83%			
Test for overall effect: Z								-2	-1 0 1 2
			'						Decrease in PA Increase in PA

	Post-intervention			Pre-intervention			\$	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Witlox 2018 (48)	579	534.1	58	853	770	118	5.8%	-0.39 [-0.71, -0.07]	
Rogers 2009 (37)	92	102	19	113.4	97.36	20	3.0%	-0.21 [-0.84, 0.42]	
Kanera 2017 (54)	512.2	425.1	206	526.5	546.5	226	7.3%	-0.03 [-0.22, 0.16]	-
Pinto 2008 (46)	78.1	91.34	39	76.98	97.23	43	4.6%	0.01 [-0.42, 0.45]	
Galvao 2017 (53)	108.2	178.4	184	105.1	184.9	231	7.3%	0.02 [-0.18, 0.21]	+
Hawkes 2013 (39)	54.3	120	163	52	112.5	205	7.2%	0.02 [-0.19, 0.23]	+
James 2015 (43)	133.1	225.7	36	120.9	201.3	46	4.6%	0.06 [-0.38, 0.49]	
Vallance 2007 (52)	142	126	96	133	144	96	6.2%	0.07 [-0.22, 0.35]	
O'Neill 2018 (49)	148	198	19	136	136.8	22	3.1%	0.07 [-0.54, 0.68]	
Sandler 2017 (47)	30.46	54.88	33	21.6	70.73	24	3.8%	0.14 [-0.39, 0.67]	
Rogers 2015 (53)	192	136	108	168	88	112	6.5%	0.21 [-0.06, 0.47]	+
Mutrie 2012 (55)	462	263	41	365	288	99	5.3%	0.34 [-0.02, 0.71]	
Pinto 2013 (56)	80.03	82.96	76	51.78	69.65	86	5.9%	0.37 [0.06, 0.68]	
Lee 2018 (50)	613.3	321.4	112	485.1	290.7	112	6.5%	0.42 [0.15, 0.68]	
Ottenbacher 2012 (44)	103.63	143.05	253	42.91	89.97	253	7.5%	0.51 [0.33, 0.68]	
Belanger 2014 (40)	118	77	48	77	71.59	48	4.8%	0.55 [0.14, 0.95]	
Pinto 2013 (45)	86.6	103.4	23	28.7	31.5	26	3.3%	0.77 [0.18, 1.35]	
Adams 2018 (42)	205.2	221.6	22	79.6	88.7	28	3.4%	0.77 [0.19, 1.35]	
Pinto 2015 (68)	63.9	82.9	31	17.1	23.4	37	4.0%	0.79 [0.29, 1.29]	
Total (95% Cl)			1567			1832	100.0%	0.21 [0.08, 0.35]	◆
Heterogeneity: Tau ² = 0.06; Chi ² = 60.41, df = 18 (P < 0.00001); l ² = 70%									-2 -1 0 1 2
Test for overall effect: Z =	= 3.08 (P	= 0.002)							Decrease in PA Increase in PA

KEEP CALM ITS THE CONCLUSION

- We need evidence but we risk excluding a significant proportion of people affected by cancer in our trials
- Interventions need to be achievable
- Cleary report intervention components and characteristics
- Debate best time to intervene
- Look beyond RCTs

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