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#### Long term health outcomes associated with an exercise referral scheme: An observational longitudinal follow-up study

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Abstract

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Background Exercise referral schemes (ERSs) support inactive adults, who have chronic health conditions, to become physically active. Uncertainty exists regarding the effectiveness of ERSs, with few studies evaluating their long term impact. The aims of this paper were to evaluate the long term impact (12 months) of participation in an ERS on self-reported physical activity (PA) and a range of health related outcomes. 

**Methods** Data were analysed for participants of a 24-week ERS who attended a week 52 follow-up between July 2015-2017. PA and health related outcomes collected at weeks 1, 24 and 52 were analysed using Friedman's test and Wilcoxon signed ranks test.

Results 273 participants attended the week 52 follow-up. Self-reported PA significantly increased by a median of 636 MET minutes at week 52. There were also significant improvements in body mass index, systolic blood pressure, mental wellbeing and health related guality of life.

**Conclusions** For every 8 participants referred to this 24-week ERS, one participant went on to show long term improvements in at least one health indicator. The evidence base requires further long term evaluations to confirm these findings across a range of ERS providers, and would benefit from the inclusion of device based measurement of PA.

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26 Introduction

> Despite increasing knowledge of the benefits of physical activity<sup>1</sup> (PA), there has been a global decline in PA levels over recent decades<sup>2</sup>. Physical inactivity is a public health challenge associated with both a substantial health<sup>1</sup> and economic burden (\$53.8 billion per annum worldwide)<sup>3</sup>. Furthermore, individuals with chronic health conditions are less likely to be active than those without<sup>4</sup>, despite the secondary prevention benefits of PA<sup>5</sup>.

One approach to PA promotion has been exercise referral schemes (ERSs), a form of non-medical intervention or 'social prescription'. Such schemes were developed in the UK in the early 1990s<sup>6</sup>, and have since been adopted in several other countries<sup>7</sup>. They aim to support inactive adults who have chronic health conditions to become more physically active in order to improve their health<sup>8</sup>. More than two decades since their development, the evidence base for the efficacy of ERSs is comparably small and inconclusive<sup>9</sup>, with further research required to understand which ERSs work, for whom and why<sup>6</sup>. 

Of the existing research, an area of focus has been the impact of participation on selfreported PA levels and health outcomes. To date, systematic reviews have found no consistent evidence of an increase in PA following participation in an ERS, or an improvement in outcomes such as body mass index (BMI), blood pressure (BP), or psychological wellbeing<sup>6,9</sup>. However, reviews have been based on a small number of randomised controlled trials (RCTs) ( $\leq$ 8), with relatively short follow-up periods ( $\leq$ 6 months). Few observational studies have been published which examine the impact

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of ERSs in real world practice settings<sup>10,11</sup>. There have also been few studies, of any design, which examine the impact of participation on long term changes in PA and health outcomes, such as 12 months or more following referral<sup>12–14</sup>. Therefore, the aims of this study were to evaluate the long term impact (12 months) of participation in an ERS on self-reported PA and a range of health related outcomes, using an observational longitudinal follow-up design.

- 58 Methods

- 60 The scheme

The ERS was delivered in the UK borough of Tameside, which is an area with evident health inequalities<sup>15</sup>, and high levels of chronic health conditions and physical inactivity<sup>15</sup>. The scheme was 6 months in duration, with 4 routine contact points (30-60 minute consultations), hosted within local leisure centres. Consultations were delivered by exercise professionals holding a minimum of a Register of Exercise Professionals (REPs) level 3 gualification in exercise referral. REPs is an independent public register that provides a system of regulation for all professionals involved in the exercise and fitness industry, with level 3 enabling the practitioner to work as an advanced fitness instructor and in exercise referral<sup>16</sup>. During an initial consultation an exercise professional made an assessment of the participant's health status, goals and preferences. Based on this information, a programme of opportunities to become physically active, tailored to the participants' needs and preferences, was then offered. This included options for supervised group-based activities, or independent activities, within the local leisure facilities (e.g. use of gym, swimming pool and PA classes) or 

the community (e.g. health walks, walking football groups, home exercises). Participants then had follow-up consultations with the exercise professional at week 6, 12, and 24, where changes in health status were assessed and behaviour change support provided, with data collection only at week 52. The ERS provided 12 months of subsidised access to its leisure facilities and supervised classes. The majority of community-based activities were free, or incurred a small pay-as-you-go fee.

Eligibility for referral

Referrals were accepted from health care professionals (including allied professions, e.g. physiotherapists) for residents of the borough aged  $\geq 18$  years, identified as inactive with a chronic health condition or significant health risk factors. Exclusion criteria included contraindications to PA<sup>17</sup>. The primary referral pathways for the scheme were: (1) existing cardiovascular disease (CVD), or significant risk factors such as hypertension; (2) metabolic syndrome or diabetes; (3) mental health condition; (4) respiratory disease; (5) overweight or obese ( $\geq 25 \text{ kg/m}^2$ ); (6) musculoskeletal condition which was chronic in nature, including pain and high risk of falls, and; (7) any other condition whose symptoms could be improved by PA (i.e. multiple sclerosis, cancer).

#### Outcome measures

The content of the data collected was dictated by the developers of the scheme, based upon the Standard Evaluation Framework for PA interventions<sup>18</sup> recommendations, and was collected by the exercise professional at weeks 1, 12, 24 and 52. The 

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outcomes included: current PA level (International Physical Activity Questionnaire Short Form<sup>19</sup> (IPAQ-SF)), health related quality of life (HRQoL) (EuroQol five dimensions three level questionnaire<sup>20</sup> (EQ-5D-3L) and EuroQol five dimensions visual analogue scale<sup>20</sup> (EQ-5D VAS)), mental wellbeing (Warwick-Edinburgh Mental Well-being Scale<sup>21</sup> (WEMWBS)), BMI, BP, alcohol consumption, and smoking status. Data management Anonymised data for referrals made to the scheme between July 2015 - July 2017 were extracted for secondary analysis. Participants who attended the week 52 follow-up were included for analysis in this study. Participants gave informed consent at the initial consultation for their anonymised data to be used for research purposes. Prior ethical approval was granted by the University of Salford ethics committee (HSCR 15-124). Statistical analysis Statistical analyses were performed using IBM SPSS version 23 (SPSS, Inc., Chicago, IL, USA). Demographics of referrals were explored using descriptive statistics. Outcomes were analysed for participants with data available at week 1 (baseline), 24 (scheme completion point) and 52 (follow-up point), on a variable by variable basis. The distribution of outcome measures was determined to be non-normal. Therefore, Friedman's test was used to examine differences in outcome measures between three time points. If the result was significant ( $p \le 0.05$ ), post hoc tests (Wilcoxon signed ranks) were performed with a Bonferroni adjustment applied ( $p \le 0.017$ ). 

1		LONG TERM ERS OUTCOMES
2 3 4	126	
5 6	127	Results
7 8 9	128	
10 11	129	Participant flow
12 13	130	
14 15 16	131	Of 2104 referrals made between July 2015 – July 2017, 1609 entered the scheme. Of
17 18	132	these, 471 had dropped out early, 515 were actively participating between weeks 1
19 20	133	and 24, and 623 had completed the scheme (attended week 24). Of those who had
21 22 23	134	completed the scheme, 230 had not yet reached the week 52 follow-up point and have
23 24 25	135	been excluded from this analysis. Of the remaining 393 participants, 273 (69.5%)
26 27	136	attended a week 52 follow-up in-person or via telephone consultation. A further 120
28 29 30 31	137	participants (30.5%) did not have a follow-up (76 unable to establish contact, 22 time
	138	elapsed beyond week 52, 20 declined, 2 died) (Figure 1).
33 34	139	
35 36	140	Participant characteristics
37 38 30	141	
40 41	142	The characteristics of participants who did or did not attend a week 52 follow-up are
42 43	143	presented in Table 1. Participants who attended the follow-up and were therefore
44 45	144	included in this analysis, were more likely to be female (56%), Caucasian (96%), and
40 47 48	145	from the most deprived quintile of Tameside (Q1, 37.4%). Participants were most
49 50	146	frequently referred from primary care medical practices (42.9%), a National Health
51 52	147	Service health trainer service (20.1%), or a weight management service (17.3%). The
53 54 55	148	most common reasons for referral were for having multiple (≥3) health conditions
56 57	149	(33%), being overweight or obese (17.6%), having a musculoskeletal condition
58 59 60	150	(16.1%) or existing CVD or significant risk factors (14.7%). Demographics, source of

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2 3 4	151	referral, and primary referral condition did not differ significantly between those who
5 6	152	did or did not attend the follow-up (Chi square $p > 0.05$ ) with the exception of age;
7 8	153	those who attended were significantly older (t(385)=2.306, $p = 0.022$ ).
9 10 11	154	
12 13	155	Participant goals
14 15	156	
16 17 19	157	A total of 192 participants (71.4%) had met their long term goals. The most frequently
19 20	158	reported goals were to reduce BMI (50%), increase or maintain PA levels (27%),
21 22	159	improve aspects of physical health such as BP (16%), and improve physical fitness
23 24	160	(11%).
25 26 27	161	
28 29	162	Physical activity
30 31	163	
32 33 24	164	There was a significant increase in self-reported PA (MET mins per week) between
35 36	165	weeks 1 (mdn 0) and 24 (mdn 660), which was maintained at week 52 (mdn 636)
37 38	166	$(\chi^2(2) = 219.9, p < .001)$ (Table 2). Post hoc tests showed that the differences were
39 40 41	167	significant between weeks 1 and 24 (Z = -11.8, $p < .001$ ), and weeks 1 and 52 (Z = -
41 42 43	168	11.9, <i>p</i> <.001).
44 45	169	
46 47 48	170	For comparison with previous research <sup>6,9</sup> , the percentage of participants who were
48 49 50	171	physically active for ≥90 minutes per week was calculated. At week 1, 17.3% were
51 52	172	active ≥90 minutes per week at any intensity, rising to 76% at week 24, but declining
53 54	173	to 72.7% at week 52 ( $\chi^2(2)$ = 231.6, <i>p</i> <.001). The differences in classification were
55 56 57	174	significant between weeks 1 and 24 ( $Z = -11.4$ , $p < .001$ ), and weeks 1 and 52 ( $Z = -$
57 58 59 60	175	11.2, <i>p</i> <.001).

177	Considering only moderate-vigorous intensity PA, the percentage of participants who
178	were physically active for ≥90 minutes per week increased from 5.5% at week 1, to
179	48% at week 24, declining to 40.2% at week 52 ( $\chi^2(2) = 212.5$ , <i>p</i> <.001). A proportion
180	of participants were active below this threshold (17.3% at week 52), and were
181	therefore not completely inactive, as can be seen in Table 3. The differences in
182	classification were significant between all three time points (all $p$ <.001). Taking the
183	conservative assumption that all those lost to follow-up made no improvement in PA
184	level, 11 referrals need to be made for one participant to become long term active (≥90
185	minutes per week at any intensity), or 19 referrals for one participant to become long-
186	term active at moderate-vigorous intensity.
187	
188	Physical health outcomes
189	
190	Participation resulted in significant reductions in body weight ( $\chi^2(2) = 68.4$ , $p < .001$ )
191	and BMI ( $\chi^2(2) = 67.5$ , $p < .001$ ). Compared to week 1, at week 52 the median reduction
192	in body weight and BMI was 3.3kg and 1.28 kg/m <sup>2</sup> respectively (Table 2). When
193	categorised according to BMI class, at all three time points the majority of participants
194	were either overweight or obese. Differences in BMI class between the three time
195	points were significant ( $\chi^2(2, n=222) = 9.0, p < 0.05$ ), but only between weeks 24 and
196	52 (Z= -2.7, $p < 0.017$ ), with a decline in the proportion classified as obese (-3.1%),
197	and an increase in the proportion classified as overweight (+0.9%) or normal weight
198	(+2.2%).
199	

2		
- 3 4	200	Compliance with BP measurement was the lowest of any outcome, with data available
5 6	201	for 29.7% of participants. There were significant improvements in systolic BP ( $\chi^2(2)$ =
7 8	202	32.6, $p < .001$ ), with post hoc tests showing significant differences between weeks 1
9 10 11	203	and 24 (Z= -4.0, p <.001), and weeks 1 and 52 (Z= -4.2, p <.001). Between weeks 1
12 13	204	and 52, systolic BP was reduced by 9mmHg from 138 (127-148) mmHg to 129 (120-
14 15	205	138) mmHg (Table 2). There were no significant differences in diastolic BP ( $\chi^2(2)$ =
16 17 10	206	5.4, $p = .069$ ). Taken together, these results indicate that an increase in PA had a
18 19 20	207	beneficial impact on body composition and systolic BP.
21 22	208	
23 24	209	Mental wellbeing
25 26 27	210	
27 28 29	211	Compliance with collection of the WEMWBS questionnaire was low, with data
30 31	212	available for 38.1% of participants. Available data demonstrated significant
32 33 24	213	improvements in mental wellbeing ( $\chi^2(2) = 48.9$ , <i>p</i> <.001). The WEMWBS score
34 35 36	214	increased from 50 (42-58) to 53 (48-59) between weeks 1 and 24 (Z = -4.4, <i>p</i> <.001),
37 38	215	and from 50 (42-58) to 55 (50-60) between weeks 1 and 52 (Z = -5.9, p <.001) (Table
39 40	216	2).
41 42 42	217	
43 44 45	218	Health related quality of life
46 47	219	
48 49 50	220	Significant improvements were found in the two measures of health related quality of
50 51	221	life, the EQ-5D-3L ( $\chi^2(2)$ = 41.9, $p < .001$ ) and EQ-5D-VAS ( $\chi^2(2)$ = 115.5, $p < .001$ )
53 54	222	(Table 2). Between weeks 1 and 24, the EQ-5D-3L score increased from .727 (.587-
55 56	223	.850) to .796 (.691-1.000) (Z = -4.3, $p < .001$ ), which was maintained at week 52 (Z =
57 58 59 60	224	-6.0, <i>p</i> <.001). The EQ5D-VAS score increased from 50 (40-70) to 70 (50-80) (Z = -

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7.3, p < .001) between weeks 1 and 24, which also was maintained at week 52 (Z = -8.8, *p* <.001). Lifestyle behaviours There were no significant differences in smoking status ( $\chi^2(2, n=268) = 2.2, p > .05$ ) or frequency of alcohol consumption ( $\chi^2(2, n=268) = 2.1, p > .05$ ). There were however significant differences in the number of alcohol units consumed per drinking episode  $(\chi^2(2, n=268) = 28.4, p < .001)$ . The number of units consumed decreased between weeks 1 and 24 (Z= -4.1, p <.001), and weeks 1 and 52 (Z= -4.5, p <.001). Number of referrals required In total 254 participants showed an improvement of any degree in at least one health indicator. Taking the conservative assumption that all those lost to follow-up made no improvement, eight referrals need to be made to have a positive impact on one person. Conclusions This aims of this study were to further previous research by reporting the long term outcomes of participation in an ERS, using an observational longitudinal follow-up design. This was important because to-date more than 600 ERSs are in operation in the UK<sup>6</sup>, and the evidence base for their efficacy is uncertain. There are a relatively small number of published evaluations, and these are predominantly RCTs evaluating 

the short term outcomes of participation, with fewer studies evaluating the sustained
impact of participation in the long term<sup>6,9</sup>.

The most important findings of this study were that participation led to significant long term improvements in PA level and the majority of health related outcomes. For every 11 participants referred, one participant went on to report long term PA behaviour change (≥90 mins per week), and for every 8 participants referred, one participant went on to show long term improvements in at least one health indicator. This conservatively assumes that those lost to follow-up have not maintained improvements at 12 months. At 6-12 months, there was a significant increase in the proportion of participants achieving ≥90 minutes of PA per week (from 17% to 73% at 12 months). There were also significant improvements in health risk factors such as BMI and BP, as well as mental wellbeing and quality of life. This indicates that participation in an ERS can lead to sustained improvements in PA and health related outcomes beyond the scheme's duration. 

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These findings are important because previous systematic reviews, which are based on a small number of RCTs, but inform policy, have found no consistent evidence for an improvement in these outcomes<sup>6,9,22</sup>. Currently there is a consensus that ERSs have a small impact on short term PA changes, with the long term impact largely unknown<sup>9</sup>. The results of this study support recent research finding significant improvements in PA over the first 6 months of participation, which are maintained in the long term (≥12 months)<sup>23</sup>. The findings are also consistent with observational studies and RCTs which found significant improvements in body composition<sup>10,11,24</sup>, systolic BP<sup>13,24</sup>, quality of life<sup>11,25,26</sup>, and mental wellbeing<sup>11,13</sup>. However, comparison 

of outcomes between schemes can be difficult, because as complex interventions with ambiguous guidance, ERSs have heterogeneous delivery models and participants, and they are often designed according to the local context and strategic aims<sup>27,28</sup>. Nonsignificant impact on lifestyle behaviours such as smoking have previously been reported, albeit rarely<sup>29,30</sup>, and suggest that ERS participation alone is not sufficient to change these behaviours, with additional specialist support required.

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A high number of referrals were made to this ERS, rising from 391 referrals in the first 6 months of operation to 2104 referrals after 2 years, which may indicate health care professional's satisfaction with the impact of the scheme. The 6 month completion rate (56.9%) was also relatively high in comparison to previous literature<sup>31</sup>, potentially demonstrating higher participant acceptance than expected. However, the most important limitation of this study is the loss to follow-up of 30.5% of participants who had reached the week 52 follow-up point. It is not possible to quantify the bias that this introduces, although we note that, other than being younger, those lost to follow-up were not systematically different at baseline. It is possible that those who were not followed up were less likely to have maintained their participation in PA. Another limitation is the self-reporting of PA, as questionnaires are subject to potential bias and subsequent poor validity<sup>32,33</sup>, with over-reporting of moderate-vigorous intensity PA, and under-reporting of light intensity PA<sup>34,35</sup>. Despite this, few studies have assessed PA levels in ERS participants using device based methods<sup>36</sup>, perhaps due to the convenience and low cost of questionnaires<sup>37</sup>. Lastly, this evaluation did not have a control group. However, the role of RCTs in the evaluation of public health interventions operating in real world contexts has received criticism<sup>38,39</sup>. The pressure for community PA interventions to conduct RCTs overlooks the skills, logistics, and 

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finances required to carry out such an evaluation<sup>40,41</sup>, and does not guarantee that an intervention designed according to the local context will have the same success in a different community.

In conclusion, referral to a 6 month ERS led to significant improvements in PA and a range of health related outcomes, which were sustained in the long term beyond the scheme's duration. This indicates that this scheme was effective in initiating and sustaining long term PA behaviour change. The evidence base requires more long term evaluations to confirm these findings, across a range of ERS providers operating in different contexts, including cost-benefit analyses, and the inclusion of device based measurement of PA to support self-reported outcomes. 

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Table 1. Demographics of participants who attended or did not attend the week 52follow-up consultation. CVD, cardiovascular disease.

	At	tended	Did	Did not attend	
	n	%	n	%	
Gender					
Female	153	56	69	57.5	
Male	120	44	51	42.5	
Age					
Mean (SD)	57.	7 (14.1)		54 (15.2)	
<65 years	175	64.1	81	67.5	
≥65 years	97	35.5	34	28.3	
Missing	1	0.4	5	4.2	
Ethnicity					
Caucasian	262	96	110	91.7	
Asian	8	2.9	7	5.8	
Mixed	-	-	3	2.5	
Black	3	1.1	-	-	
Employment status					
Full time employed	58	21.2	31	25.8	

1			LONG TE	RM ERS OUT	COMES
2 3 4	Part time employed	22	8.1	10	8.3
5 6 7	Unemployed	42	15.4	26	21.7
8 9 10	Retired/other	151	55.3	53	44.2
11 12 13	Unknown				
14 15 16	Quintile of deprivation				
17 18 19	1 (most deprived)	102	37.4	45	37.5
20 21 22	2	77	28.2	33	27.5
23 24 25	3	38	13.9	16	13.3
26 27 28	4	42	15.4	15	12.5
29 30 31	5 (least deprived)	10	3.7	6	5
32 33 34	Unavailable	4	1.5	5	4.2
35 36 37	Source of referral				
38 39 40	Medical Practice	117	42.9	55	45.8
41 42 43	Health trainers	55	20.1	19	15.8
44 45 46	Physiotherapist	25	9.2	14	11.7
47 48 49	Weight management	47	17.3	15	12.5
50 51 52	Other service	29	10.5	17	14.2
53 54 55	Primary referral condition				
50 57 58 59	CVD/High risk of CVD	40	14.7	18	15

Diabetes/Pre-diabetes	18	6.6	3	2.5
Mental health	12	4.4	6	5
Respiratory	12	4.4	2	1.7
Musculoskeletal	44	16.1	23	19.2
≥Overweight	48	17.6	23	19.2
Other condition	9	3.3	1	0.8
Multiple	90	33	44	36.7

Pee perez

Table 2. Median (IQR) outcomes for each variable, at each time point. W=week. W1-W24, W1-W52, and W24-W52 detail the median change in each outcome between the two respective time points. \*<.05, \*\* <.01 (Wilcoxon signed rank test)

Outcome	n	W1	W24	W52	W1-	W1-	W24-
					W24	W52	W52
Sitting time	269	480 (360-	420 (300-	360	-60**	-120**	-60
		660)	480)	(300-			
				480)			
MET mins	271	0 (0-198)	660 (360-	636	+660**	+636**	-24
			960)	(248-			
				960)			
Kilocalorie	223	0 (0-289)	1051	941	+1051**	+941**	-110
expenditure			(582-	(461-			
			1583)	1456)			
Body weight	224	91.3	89 (76.8-	88 (76.1-	-2.3**	-3.3**	-1.**
		(76.75-	104.8)	104)			
		107.2)					
BMI	222	32.7	31.68	31.42	-1.02**	-1.28**	-0.26**
		(27.82-	(27.68-	(27.51-			
		37.64)	36.91)	35.99)			

Systolic BP	81	138 (127-	131 (120-	129	-7**	-9**	-2
		148)	140)	(120-			
				138)			
Diastolic BP	81	80 (75-89)	80 (73-	81 (76-	0	+1	+1
			85)	85)			
EQ-5D-3L	266	.727 (.587-	.796	.796	+.069**	+.069**	0*
		.850)	(.691-	(.691-			
			1.000)	1.000)			
EQ-5D VAS	266	50 (40-70)	70 (50-	70 (50-	+20**	+20**	0**
			80)	80)			
WEMWBS	104	50 (42-58)	53 (48-	55 (50-	+3**	+5**	+2**
			59)	60)			
				0			

Table 3. Number of participants who were inactive, or active above or below the 90minutes of moderate-vigorous intensity physical activity (PA) per week threshold at each time point (N= 271).

	We	Week 1		Week 24		Week 52	
PA threshold	n	%	n	%	n	%	
0 minutes	236	87.1	85	31.4	115	42.4	
1-89 minutes	20	7.4	56	20.7	47	17.3	
90+ minutes	15	5.5	130	48	109	40.2	



167x88mm (72 x 72 DPI)