

**The Role Of Self Determination In Changing Physical Activity Behaviour In People
Diagnosed With Bowel Polyps: A Pilot Randomised Controlled Trial**

Abstract

Background

This non-blinded randomised controlled trial investigated the efficacy of a physical activity (PA) intervention underpinned by Self-Determination Theory (SDT).

Methods

Participants (n=31, mean age 69y [SD= 4.9]) diagnosed with bowel polyps were randomised to active lifestyle programme (ALP; N= 17) or standard care (SC, N=14). ALP received supervised exercise and counselling for 6 months. Both groups were followed-up at 12 months. Outcomes were change in PA and behavioural regulation. Data were analysed with intention-to treat.

Results

At 6 months differences were observed for behavioural regulation in favour of ALP ($P<0.05$). PA differences were significant for leisure, walking, and vigorous in favour of ALP ($P<0.05$).

Conclusion

SDT can be an effective strategy for promoting PA behaviour change in this population but a larger trial is needed to further explore utility of SDT in this context.

Introduction

Older age is the most important risk factor of most cancers with 25.4% of all cancers occurring in people aged 65-74 years of age, compared to less than 14.1% in people aged 54 years and younger (National Cancer Institute, 2015). In the UK, the incidence of colorectal cancer (CRC) rises steeply from age 50-54y and the highest rates are in people aged 85-89y (Cancer Research UK, 2018).

Besides age as a risk factor, there is now convincing evidence that the risk of developing CRC is associated with lifestyle behaviours such as a diet and low levels of physical activity (PA) (World Cancer Research Fund, 2018). It was estimated that up to 21% of all CRC cases could be prevented if everyone in Europe adhered to 30 min of moderate PA per day (de Vries et al., 2010).

The UK National Bowel Cancer Screening Programme aims to detect CRC before symptoms occur for earlier treatment and better survival and is offered to older people aged 60-74y (Public Health England, 2017). Recent data suggest that the risk of a recurrence of adenoma is around 40% at three years post-removal (Kitahara et al., 2013). While removal of a polyp or adenoma may be associated with reduced risk of developing CRC, underlying lifestyle risk factors on the causal pathway may continue to be present.

Considering the benefits of PA in the prevention of CRC, it is concerning that levels of PA reduce with increase in age (Health Survey England, 2016). Sixty-seven percent of adults aged 19-64y met the PA guidelines for aerobic activities in 2016, and only 44% of adults aged 65y and over met these guidelines. Where age is an unavoidable risk factor, PA is not and there is a need to support uptake of PA in this population.

A polyp diagnosis after screening by colonoscopy could act as a ‘teachable moment’ and thus, may present an opportunity to offer health advice **to this population** (McBride et al., 2008). Interventions in adults identified with polyps or adenomas aimed at changing several risk behaviours were found to be effective at changing dietary behaviour (McCahon et al., 2015). However, evidence for PA behaviour change remains limited (Anderson et al., 2014).

In particular, there is a lack of evidence supporting the effectiveness of PA interventions with respect to long-term PA behaviour maintenance in people at increased risk of developing CRC (McCahon et al., 2015). A Cochrane review (Foster, Hillsdon, & Thorogood, 2005) on interventions for promoting PA concluded that studies are effective at least in the short-term but long-term effectiveness is not established. Furthermore, interventions that were successful in maintaining PA behaviour in the long-term were those that included a maintenance intervention, which is either a repeat of the initial intervention or the use of booster strategies (Muller-Riemenschneider, Reinhold, Nocon, & Willich, 2008). This approach does not appear to be cost-effective and PA levels could drop again after the maintenance intervention ceases. Guidance for the development of complex interventions by the Medical Research Council (Craig et al., 2008) recommends that theory should inform intervention development to advance the field of behaviour change research (Prestwich et al., 2014). In this context, we designed an intervention, underpinned by Self-Determination Theory (Deci & Ryan, 1985), aimed at increasing PA behaviour in people at elevated risk of CRC.

Our main objective was to examine the effect of the intervention on PA behaviour and underlying motivation to change. It was hypothesised that participants in the intervention group would demonstrate higher PA levels at 6 months (post-intervention) than the comparison group. A secondary exploratory aim was to obtain preliminary data on the effectiveness of this intervention on behavioural regulation, and physiological outcomes. More specifically, we were interested in the potential of this intervention to change behavioural regulation from a

more extrinsic regulation to a more autonomous regulation, elicit changes in body composition, and improvements in aerobic fitness. Lastly, the maintenance of these changes were investigated at 12 months of follow-up.

Self-Determination-Theory

The theory proposes that motivation to engage in a specific behaviour can be conceptualised along a continuum of relative autonomy (Deci & Ryan, 1985). In other words, motivation can be very autonomous if the behaviour is internalised, or less autonomous if the behaviour is not part of the person's sense of self (Deci, Cascio, & Krusell, 1975). The different quality of regulations ranges from feelings of low autonomy to feelings of high autonomy. From the least autonomous to the most autonomous these are: *amotivation, external regulation, introjection, identification, integration, and intrinsic motivation*. The theory states, that satisfying three psychological needs (*autonomy, competence, relatedness*) will lead to a shift from low to high autonomous regulation (Deci & Ryan, 2000). Autonomous regulation has been related to higher attendance to exercise regimes (Ryan, Frederick, Lepas, Rubio, & Sheldon, 1997), higher attendance at intervention programmes (Williams, Grow, Freedman, Ryan, & Deci, 1996), higher maintenance rates of health behaviours such as smoking cessation (Williams et al., 2009), weight loss (Silva et al., 2010; Williams et al., 1996), and higher levels of PA (Milne, Wallman, Guilfoyle, Gordon, & Corneya, 2008; Mullan, Markland, & Ingledew, 1997; Standage, Sebire, & Loney, 2008, Chatzisarantis & Hagger, 2009; Wilson, Rodgers, & Fraser, 2002; Wilson, Blanchard, Nehl, & Baker, 2006), making it a promising theory for this PA intervention.

Application of Self-Determination Theory in Physical Activity Interventions

Interventions in the PA domain have applied SDT and demonstrated its potential for successful behaviour change. In a study comparing the effects of two different exercise teaching styles

(teacher's normal style vs autonomy-supportive style) resulted in higher attendance, greater increase in competence, and relatedness, but not higher introjection in the autonomy-supportive taught class (Edmunds, Ntoumanis, & Duda, 2008). The lack of difference in introjection might be due to a £50 prize draw incentive for participants. Monetary rewards have shown to be thwarting intrinsic motivation. A 12-week PA counselling in primary care study (PAC trial) based on SDT showed significant differences in levels of PA and autonomy support index in favour for the experimental group (Fortier et al., 2007). One trial based on SDT also examined long-term maintenance of PA behaviour after intervention and showed that still after 3 years of the intervention, obese women in the experimental group had significant higher levels of levels of PA, and weight loss (Silva et al., 2011). Despite the promising findings of PA trials using SDT additional research needs to explore the usefulness of this theory in changing PA behaviour in an elderly population.

Methods

Study Design

This was a 2-armed non-blinded, parallel randomised controlled trial (RCT) with equal sample size. Participants (n=31) with bowel polyps were equally randomised to either the 6-months active lifestyle programme (ALP) or the control group (SC) which received standard care. Outcome measures were assessed at baseline (BL), 6 months, and 12 months (6 months after withdrawal of supervision). Participants were recruited on a rolling basis from September 2012 to February 2014 and were randomised after completion of baseline measures.

Ethical Considerations

The study has received ethical approval by the XXXX Research Ethics Committee and was registered on clinicaltrials.gov, ID NCT02724306 (<https://clinicaltrials.gov/ct2/show/NCT02724306>).

Participants And Setting

Participants were patients with a positive diagnosis of colorectal polyps or adenomas and were identified either via the *UK National Bowel Cancer Screening Programme* or colonoscopy attendance register at the [*insert NAME OF HOSPITAL*]. Inclusion criteria were (i) a diagnosis of a polyp or adenoma during a screening colonoscopy, and ii) >60 years of age. Exclusion criteria were (i) already meeting the current physical activity guidelines of 150 min moderate or 75 min vigorous intensity physical activity per week (Haskell et al., 2007); (ii) history of cardiovascular/pulmonary disease or stroke; (iii) diagnosis of type 2 diabetes mellitus; (iv) presence of other colorectal conditions (e.g. inflammatory bowel disease), known familial colorectal cancer syndrome or previous bowel cancer diagnosis; (v) and inability to adequately understand written and spoken English.

Recruitment of patients took place via three different routes; (i) Recruitment via specialist nurses, (ii) invitation letter from a consultant, and (iii) recruitment via clinics. At first contact, patients were given a patient information sheet. If first contact was with a health professional, consent to be contacted by a researcher, was sought. Patients receiving invitation letters were provided with the researchers' contact details, enabling them to express an interest in the study. Researchers telephoned the patient within one week of first contact and if the patient was interested, a meeting was scheduled at the [*insert name of University Institution*], where screening for eligibility was undertaken and the consent form signed.

Participants were recruited over a period of 16 months (September 2012 to January 2014). The recruitment end-point was determined based on the ability to follow-up participants for 6 months post-intervention, and to allow time for data analysis within the proposed time-frame of the study.

Outcome Measures

All outcome measures were assessed at baseline after consent was taken, and repeated at 6 months and 12 months.

Primary Outcome Measures. Physical activity was assessed objectively and subjectively using the following tools: *Objective PA* was assessed with an accelerometer (ActiGraph® GT3X, FL, USA) over a period of seven days and presented as accumulated moderate-vigorous PA (MVPA), i.e. the sum of all movements above 1952 counts per minute (Freedson, Melanson, & Sirard, 1998), and as the sum of all movements in bouts of >10 min. The epoch period was set at 1 min (Freedson et al., 1998; Hendelman, Miller, Baggett, Debold, & Freedson, 2000; N. E. Miller, Strath, Swartz, & Cashin, 2010). Each participant was instructed on the correct wear position (around the waist and above the right iliac crest), to take off the device during night-time sleep and water activities, and to wear it for at least 5 days in a seven day period. Records were included if wear-time was at least 10h per day on a minimum of 5 days including a weekend day (Choi, Liu, Matthews, & Buchowski, 2011).

Self-reported PA was assessed with the International Physical Activity Questionnaire (IPAQ), which measures four domains of PA: (i) occupational; (ii) transportation-related; (iii); household/house maintenance, and (iv) recreation-related (Hagstromer, Oja, & Sjostrom, 2006). Occupational and household related PA were combined because the majority of

participants did not report any occupational PA. The validity of the IPAQ has been rated as acceptable for total PA and the different activity domains (Hagstromer, Oja, & Sjostrom, 2006). The questionnaire was delivered in an interview-form with each participant to minimise potential over-reporting. Interview-delivery of the questionnaire has shown acceptable validity (Lewis, Hernon, Clark, & Saxton, 2017).

Secondary Outcome Measures. The *Behavioural Regulation for Exercise Questionnaire* version 2 (BREQ-2) was used to assess motivational regulation for exercise (Markland & Tobin, 2004). The questionnaire measures *amotivation, external, introjected, identified* and *intrinsic regulation*. Responses to the 19-item questionnaire were scored on a 5-point Likert scale ranging from 0= “Not true for me” to 4= “very true for me”. Results are scored as means from all items in each subscale and therefore, the possible range is 0-4. A relative autonomy index (RAI) can be derived from the subscales and provides the level of self-determination with higher scores corresponding to higher self-determination (Markland & Tobin, 2004). The highest possible score for RAI is 20. **Previous data has demonstrated excellent validity of the BREQ-2 (Markland & Tobin, 2004).**

Body composition was measured using standard techniques. Body mass index (BMI) was determined from body height and weight. Body fat was analysed using impedance (AKERN BIA 101, Pontassieve, Italy) and waist and hip circumferences measured using an anthropometric tape (Seca 201, Hamburg, Germany).

Cardiorespiratory fitness was measured as maximal aerobic capacity ($\dot{V}O_{2max}$) and assessed on an electronically braked cycle ergometer (Excalibur Sport, Lode, Netherlands). Following a 2 min freewheeling-period, the intensity increased every 2 min by 15 Watts until volitional exhaustion. Heart rate was recorded continuously by ECG (Cardioperfect, Welch Allyn USA)

and expired gases were measured breath by breath using an on-line expired gas analysis system (Ultima, CardioO2; Medical Graphics Corporation).

Intervention

Supervised exercise sessions (n=36) were offered to the ALP group twice a week for three months and once a week for the following three months. Exercise sessions started with a 5-10 min warm-up, and were followed by 30 min of aerobic exercise at 65-85% of maximum heart rate (as determined by a maximal cardiopulmonary exercise test), 10-15 min of resistance exercise and a 5-10 min cool-down. The exercise programme was progressed according to individual capabilities to maintain an adequate stimulus for adaptation.

Behaviour change workshops (n=12) to aid the uptake and maintenance of physical activity were delivered once a fortnight for 6 months. All workshop topics by week can be found in table 5. The workshops were delivered in a motivational interviewing (MI) style (W. Miller & Rollnick, 2012) and aimed to facilitate behaviour change by addressing the three psychological needs of SDT. This included for example providing a rationale, providing support, using supportive language (avoid 'have to', 'must'), and provide choice (Deci & Ryan, 2000). To support maintenance of PA behaviour, participants were also encouraged to sign up with local GP Exercise Referral Schemes (if they were eligible) and to identify and join a community-based exercise programme. In the UK, medical professionals can make referrals of patients to community-based exercise programmes. The programme is run by local authority leisure centres and typically lasts 12 weeks. The exercise instructor organised group visits to the local gym to introduce participants to publicly available exercise programmes. Supervised exercise sessions and SDT workshops were led by the same person who is a Level 2 Register of Exercise Professionals (REPs) Exercise Specialist and a trained motivational interviewer. In addition,

all participants received pedometers to monitor their daily step counts. These data were not collected as they were intended as a motivational tool.

The person leading the exercise sessions and workshops created an autonomy-supportive environment, in accordance with the tenets of SDT (Deci, Eghrari, Patrick, & Leone, 1994). This was achieved by (i) providing a meaningful rationale (e.g. why certain modes of exercise were chosen, what are the health benefits of the exercises, etc.), (ii) acknowledging participant perspectives on the exercises (e.g. they might be difficult at the beginning if inexperienced, might experience elevated breathing, etc.), (iii) conveying choice rather than control (e.g. choice of mode of exercise, choice of personal reasons for wanting to exercise, etc.), and (iv) providing positive informative feedback on their progress.

Randomisation

Participants were randomised to one of two groups (ALP or SC) using nQuery (Statsol, USA) which generated a randomisation list which was held by an independent researcher who was not involved in the day-to-day running of the trial. To minimise selection bias, the researcher carrying out the intervention did not receive the allocation sequence until all baseline assessments were completed using *Covariate Adaptive Randomization*.

Blinding

Because of the nature of the trial, the researcher carrying out the intervention could not be blinded to the group allocation. However, the person conducting the fitness tests was blinded to the group allocation.

Data Analysis

Data were analysed with the Statistical Package for the Social Sciences (SPSS) version 22. Baseline data were analysed for group differences based on the originally assigned groups,

using independent t-tests. Normality was examined with the Kolmogorov-Smirnov test. Non-parametric tests were used if the data was non-normally distributed. Group differences in changes from baseline to post-intervention and follow-up were analysed using a mixed effects model analysis, adjusted for baseline values, with group allocation as fixed effects. Statistical significance was set at $P < 0.05$. Data were not imputed because imputation has been shown to be flawed in longitudinal studies with large amount of missing data (Lane, 2008). The mixed model analysis included the following number of participants at each time point: BL: n= 31, 3 months: n=27, 6 months: n=22, 9 months: n=15, 12 months: n=15. This was chosen because the data violated normality, and sphericity, and a large % of data were missing at 6, and 12 months, all of which could result in loss of power and type I error and mixed model analysis was shown to be more reliable (Armijo-Olivo, Warren, & Magee, 2009; Fields, 2005).

Results

There were no group differences of any outcome measures at baseline. The baseline characteristics of the study participants are shown in Table 1.

[Insert Table 1 here]

Participant flow

The flow of participants through the study is shown in Figure 1. A total of 31 participants were randomised to the intervention (n= 7) or the standard care (n=14) conditions. At the primary end-point (6 months), 71% (n=22) of the randomised participants were still available for post-intervention assessments. At 12 months only 48% (n=15) were available for follow-up; two were unable to be contacted and five could not be followed-up due to end of study prior to the follow-up time for those participants.

[Insert Figure 1 here]

Intervention Compliance and adverse events

Compliance at the supervised exercise sessions was 72% with an average of 28 of 36 supervised exercise sessions being attended. Reasons for non-attendance were commonly health reasons (feeling unwell), being on holidays, having family commitments, work commitments or appointments. Workshop attendance was 65% (mean of 7.8 out of 12 workshops). Reasons for non-attendance were the same as for supervised exercise. There were no adverse events resulting from the intervention.

Health Outcomes

Post-intervention (6 months). For self-reported PA behaviour, leisure-time PA, walking-time PA and vigorous PA were significantly different between the groups at 6 months, with ALP reporting 163 min more than SC (95% CI: 20 to 301, $P=0.02$, effect size=0.95) of leisure-time, 150 min more of walking-time (95% CI: 34 to 268, $P=0.02$, effect size= 1.24) and 38 min more of vigorous PA per week (95% CI: 8-68, $P=0.02$, effect size=1.18), (Table 4).

Significant group mean differences were observed for amotivation (-0.7; 95% CI:-0.1 to -1.0, $P=0.03$, effect size=-0.61), identified regulation (0.9; 95% CI= 0.2 to 1.6, $P=0.01$, effect size=1.04), intrinsic regulation (1.6; 95% CI: 0.9 to 2.2, $P<0.001$, effect size=1.81), and RAI (7.8; 95% CI: 2.9 to 12.0, $P<0.001$, effect size=1.09) in favour of ALP at 6 months (Table 3).

Cardiopulmonary fitness increased in ALP and remained unchanged in SC, with a mean difference of 2.6 ml·kg⁻¹·min⁻¹ (95% CI: 0.5 to 4.8 ml·kg⁻¹·min⁻¹, $P=0.02$, effect size=0.05) at 6 months.

Follow-up (12 months). ALP had a smaller increase in body fat than SC at the 12 month follow-up (0.8% vs 3.3%, 95% CI: 1.2 to 6.8, $P=0.01$, effect size= 0.14), (Table 2). Self-

reported PA outcomes showed significant differences between the groups, with more leisure-time PA in ALP vs SC (302min vs 36min, $P<0.001$; effect size=1.69), (Table 4). No other IPAQ domains or objective PA outcomes (derived from accelerometry) showed significant group differences.

The changes in behavioural regulation were not maintained at the 12 month follow-up but there was still a difference between the groups in intrinsic regulation in favour of ALP (1.5; 95% CI: 0.0 to 2.4, $P=0.05$; effect size=0.98), (Table 3). The positive changes in cardiopulmonary fitness in ALP at 6 months were maintained at the 12 month follow-up but there was no difference between the groups at this time-point.

[Insert tables 2-4 here]

Discussion

This study was novel in that it tested an SDT approach to promote PA in **an aging population participating in the bowel cancer screening**, an area that is understudied. We demonstrated that such an approach is promising in the uptake and long-term maintenance of PA behaviour change as positive changes in behavioural regulation towards more intrinsic regulation and improvements in leisure-time PA were still present at 12 months.

Currently, evidence for the long-term impact of PA behaviour change interventions is limited (Foster et al., 2005; Müller-Riemenschneider, Reinhold, Nocon, & Willich, 2008). And if behaviour change maintenance was achieved, then often with the use of an additional intervention during the maintenance period (Foster et al., 2005). The present study did not have any contact with participants in the follow-up period and was designed to develop the skills and confidence for continued autonomous PA behaviour post-intervention. Such an approach is more pragmatic and has the potential to be more economically viable.

The ability to test this approach with a larger sample size was hampered by poor recruitment. The rural area in which the study took place could have contributed to this as travel distances may have been a barrier. Furthermore, the intervention may have been time consuming, as it required twice weekly visits to the research site. Home-based exercise trials have reported better recruitment rates (32-61%) (Emmons et al., 2005; Treweek et al., 2013). Both these reasons have previously been cited as major recruitment barriers for research participants (Gul & Ali, 2010). Besides these barriers related to trial characteristics, it is likely that personal reasons and health reasons contributed to this low recruitment. An older population is more likely to suffer from multi-morbidities (Barnett et al., 2012) leading to more frailty in this population (Cesari, Landi, Vellas, Bernabei, & Marzetti, 2014).

Our first hypothesis, that an SDT-based intervention would increase PA behaviour at 6 months was supported, although only leisure-time PA was found to be significantly increased at 6 months. This is encouraging though, because leisure activities have been shown to decline the most with increasing age (Armstrong & Morgan, 1998) whereas walking is more likely to increase (Päivi, Mirja, & Terttu, 2010). Positive changes in PA behaviour were also maintained at the 12 month follow-up. This is also important for the aging population as in general PA levels tend to decline with older age (Scholes, 2017).

We were also able to show that the ALP group had higher intrinsic motivation at both time points than the SC which is consistent with previous research in other populations which show that autonomy supportive environments facilitate internalization of motivation to a more autonomous regulation (Fortier, Sweet, O'Sullivan, & Williams, 2007; Hartmann, Dohle, & Siegrist, 2015; Markland, 1999; Silva et al., 2010; Standage et al., 2008; Van Hooeck, Delecluse, Bogaerts, & Boen, 2014). Furthermore, a systematic review investigating the relationships between SDT variables and exercise behaviour found that intrinsic regulation was the strongest predictor of exercise behaviour (Teixeira, Carraça, Markland, Silva, & Ryan,

2012). Therefore, it is likely that the intervention effects on motivational regulation contributed to the positive changes in PA behaviour in our sample via facilitation of the psychological needs; autonomy, competence, and relatedness (Markland, 1999). In particular, the components of this study were designed to satisfy those needs, with strategies such as frequent contact with participants, providing positive feedback and providing choice over mode of activities. The same person delivered all supervised sessions and participants could have formed a close relationship thus, further satisfying the need for relatedness. However, we did not test whether components of the intervention supported the three needs proposed by SDT. Therefore interpretation of the findings in this context is limited. Further research is needed and it is recommended to test the satisfaction of the psychological needs of participants to identify the components of the intervention that have contributed to positive changes. A larger sample size for such an investigation is needed.

Although, this study addresses behaviour change in an older population diagnosed with bowel polyps, other important benefits of increased levels of PA to older peoples should not be ignored. More PA also provides prevention of chronic diseases (Warburton, Nicol, & Bredin, 2006) as well as improved physical, mental, social and spiritual well-being (Adams-Fryatt, 2010). This study has shown that providing a lifestyle intervention to people attending the screening colonoscopy might be a potential route to promoting behaviour change. In this study only people with a polyp diagnosis were invited to take part, but the screening setting could provide the opportunity for health care professionals (HCPs) to provide information on suitable PA programmes to all people attending the screening colonoscopy. This would capture at least all people aged 60y and over who were identified as risk patients and were then invited to the screening colonoscopy. The uptake of screening was 57.9% between 2012-2015 and of those who had an abnormal screening result 79% attended the colonoscopy (Koo, Neilson, Von Wagner, & Rees, 2017). This would at least be one avenue to offer lifestyle programmes to

older peoples. People could be referred to existing programmes, such as the GP referral programme. It is also possible to deliver the GP referral programme using an autonomy-supportive style in accordance with SDT to support internal regulation of behaviour change (Duda et al., 2014). Such avenues should be tested to bridge the gap between research and societal practice (Freiberger et al., 2019).

Strength and Limitations

The main strengths of the study were the randomised controlled design, the long-term follow-up, and a theory-based intervention. However, our preliminary data need to be interpreted in the context of the study limitations. Firstly, the sample size was small and we were unable to follow-up all participants. This introduced bias due to large amount of missing data, but also a lack of statistical power to detect changes in some study outcomes. Secondly, using intention-to-treat analysis may reduce the efficacy of the intervention due to non-compliers in the interventions group. Thirdly, ascertainment bias was introduced to the study because the researcher who delivered the intervention was not blinded to group allocation. Finally, an assessment to test whether psychological needs proposed by SDT were satisfied should have been included to assess which components contributed to positive changes in behavioural regulation and PA levels. However, this was only a pilot study, and a larger sample size is need to gain meaningful data to aid this investigation.

Conclusion

Our results suggest that ALP underpinned by SDT has the potential to evoke a change in PA behaviour, consistent with a shift in motivation from a more external regulation to a more internal regulation in elderly people diagnosed with colonic polyps. Furthermore, our preliminary findings indicate that the intervention was successful in maintaining changes in

behavioural regulation and increased time spent in leisure-time PA beyond the period of supervision at 12 months of follow-up. An adequately powered RCT is needed to confirm these preliminary findings, and the period of follow-up should be extended beyond 12 months.

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