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Effect of a Physical Activity Consultation in the Management of Adolescent Overweight (the PAC-MAnO project): study rationale, design and methods

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ABSTRACT

Background Adolescent overweight is a major public health concern, as it is associated with several short-run and long-run adverse health outcomes. Inappropriate health behaviours may be at the front of this epidemic. There is widespread need for new strategies that may positively influence dietary and physical activity behaviours. This trial (NCT02941770) was designed to investigate the impact of a physical activity consultation, based on motivational interview technique, on physical activity behaviour and weight status among overweight adolescents followed at a tertiary paediatric care centre.

Methods/Design This is an ongoing non-randomised controlled clinical trial with a 6-month duration and follow-up at month 12. It is expected to be concluded in December 2018. Adolescents (n=129) aged 12–18 with a body mass index ≥p85 are recruited and allocated into three groups: (1) control group: standard care (paediatric and nutrition consultations, n=43); (2) experimental group I: standard care plus physical activity consultation (n=43); and (3) experimental group II: exposure to two sessions/week of structured physical exercise, in addition to the standard care plus physical activity consultations (n=43). Sample size was calculated according to power analysis. Participants undergo a set of socioeconomic, anthropometric, body composition, clinical and behavioural (dietary and physical activity) assessments.

Discussion Adolescence is a critical period for the acquisition of a healthy lifestyle. The promotion of an active lifestyle may influence adolescents' weight status and further prevent multiple comorbidities. The findings of our study will provide further understanding on the impact of a physical activity consultation on physical activity behaviour and weight reduction/maintenance among overweight adolescents.

Trial registration number NCT02941770.

BACKGROUND

Paediatric obesity is a public health concern worldwide[1] and one of the greatest health challenges of the 21st century.[2] According to the observations from the Health Behaviour in School-aged Children from the WHO, the prevalence of obesity has increased between 2002 and 2014 in more than half of the European countries.[3] In Portugal, it is estimated that about 3% of adolescents are obese and 30% are overweight.[4]

Even at younger ages overweight is associated with several adverse health conditions, such as cardiovascular,[5] metabolic[6] and psychosocial comorbidities.[7 8] In addition, adolescent overweight is recognised as an independent risk factor for adult overweight and increased mortality.[9–11]

Weight management is particularly complex, and is crucial in adolescence since there is evidence that (1) physical activity (PA) levels tend to decline in adolescence[12 13]; (2) adolescence represents a transitional stage from child to adulthood associated with a substantial energy efficiency and a decrease in the resting metabolic rate[14]; (3) adolescence is the last critical period of adipocyte differentiation,[15] with the number of adipocytes remaining unchanged thereafter[16]; and (4) adolescence is associated with significant psychological changes,[17] being recognised as a critical period for acquisition of healthy behaviours.[18]

Recently, several authors and international associations, such as the European Association for the Study of Obesity, have considered obesity as a chronic condition, highlighting the idea that the management of obesity, prior to the appearance of overweight-related comorbidities, is crucial.[2]

Health institutions play a crucial role in the management of obesity. It has been suggested that a chronic care model may be implemented, with integration of healthcare, community resources and promotion of patient self-management for an effective management of obesity.[19] According to the Expert Committee recommendations

regarding the prevention, assessment and treatment of child and adolescent overweight and obesity (2007), healthcare institutions should be organised in multidisciplinary teams including paediatricians, nutritionists, psychologists and exercise physiologists in order to be able to screen and handle co-occurring morbidities, and for diet and PA counselling.[20] PA has been recognised as having a beneficial effect on energy expenditure and as having an independent effect on physiological[21] and psychological health.[22]

The Pediatric Obesity Clinic at Hospital de Santa Maria (Lisbon, Portugal) follows these recommendations since 2007. The team comprises paediatricians, nutritionists, psychologists and exercise physiologists. To the best of our knowledge, this is the first and only Portuguese tertiary healthcare centre including an exercise physiologist in their multidisciplinary team and having established the PA consultation into routine care.

PA consultation is a structured form of PA counselling based on the transtheoretical model.[23] It has been suggested to be an effective and inexpensive[24] method of enhancing PA behaviours, weight status[25 26] and self-management/autonomy,[27] as well as improving several biochemical markers among overweight youth.[28] However, due to the inconsistent results reported in the literature on the effect of PA counselling on PA behaviours and weight status, a further understanding of the benefits of including PA consultation as part of a paediatric obesity management programme is needed.

METHODS/DESIGN

Trial design

This study was designed as a non-randomised controlled clinical trial with two phases. Phase I corresponds to the intervention phase, with a duration of 6 months. In this phase eligible participants are allocated by consecutive sampling[29] into three groups: (1) control group: standard care (paediatric and nutrition consultations); (2) experimental group I: standard care plus PA consultation; and (3) experimental group II: 2 weekly physical exercise sessions on top of the standard care and PA consultations. Phase II consists of a passive 6-month follow-up, wherein the participants in both the experimental and control groups will not receive any intervention, but will have to attend a scheduled appointment with the paediatrician as part of the standard care protocol. The participant's ability to maintain PA levels and a healthy weight status will be monitored by the end of the follow-up (at month 12). The clinical trial is being conducted at the Pediatric Obesity Clinic, Department of Pediatrics, Hospital de Santa Maria, Lisbon, Portugal, in collaboration with the Exercise and Health Laboratory, Faculty of Human Kinetics, University of Lisbon, Lisbon, Portugal. It is estimated that the present trial will be concluded at the end of December 2018.

Aims and hypotheses

The main aim of this study is to assess whether the adolescents exposed to a PA consultation (with or without the participation in 2 weekly physical exercise sessions), as part of a multidisciplinary programme for the management of adolescent overweight, show higher improvements in their body mass index (BMI) z-score, PA levels and sedentary behaviour outcomes at 6 and 12 months, compared with those only exposed to the standard care. We hypothesise that (1) at the end of phase I, the participants in experimental group II will show higher improvements in their BMI z-score and PA levels, but not in sedentary behaviours, compared with the participants in experimental group I and in the control group. The increase in PA levels resulting from the participation in the scheduled physical exercise sessions, and the associated increase in energy expenditure, may lead to a higher decrease in BMI z-score in experimental group II. It will be expected that motivational interview will play a higher influence in experimental group I compared with experimental group II, since the reduced contact time with a health professional may stimulate participants' autonomy as well as their perception of self-efficacy in case of success in achieving individual goals. It is expected that experimental group I may show the second highest increase in PA levels, as well as the second highest decrease in BMI z-score. Based on the interaction between participants and health professionals in experimental group II, we hypothesise that sedentary behaviour will be maintained in this group, but will decrease in experimental group I. We further hypothesise that (2) at the end of phase II, participants in experimental groups I and II will show similar results as regards to BMI z-score, but neither in PA nor in sedentary behaviours. During the passive period, we expect that participants in experimental group II will maintain their BMI z-score. However, due to the end of the scheduled physical exercise sessions and decreased contact time with health professionals, we expect that experimental group II participants will show decreased PA levels and higher sedentary behaviours than group I participants, who may maintain both PA and sedentary behaviours (compared with phase I). The expected results on BMI z-score, based on previous published[26] and unpublished research, are illustrated in figure 1.

This study has secondary objectives. The first is to analyse the effect of the intervention on cardiorespiratory fitness (CRF). CRF is commonly expressed as VO_2 max (maximum amount of oxygen consumption) and represents the ability to uptake, deliver and use oxygen to produce energy.[30] CRF is inversely associated with BMI and waist circumference,[31] and has a potential beneficial effect on the endothelial function and structure (which is known to be impaired among overweight adolescents) even without the occurrence of major changes in the BMI.[32 33] The second objective is to analyse whether changes in BMI z-score, body composition, PA/sedentary behaviour and CRF are associated with changes in the endothelial structural health (assessed trough carotid

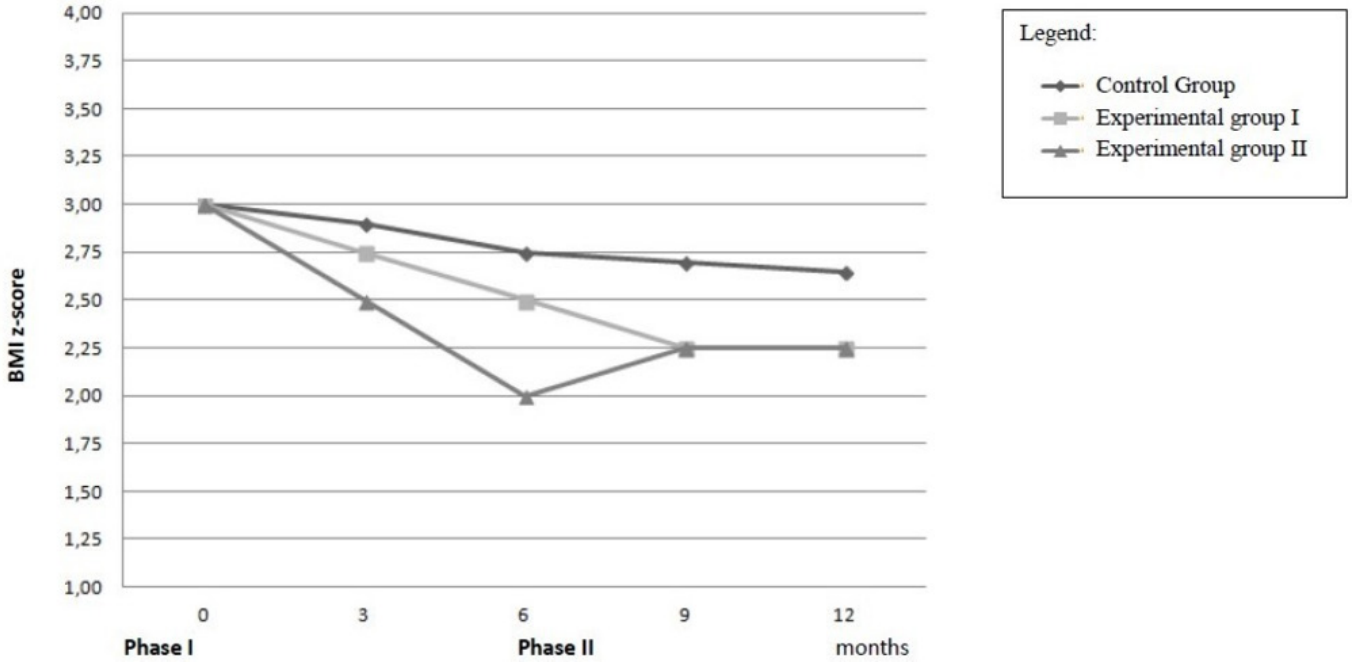

Figure 1 Expected results of the study. BMI, body mass index.

intima-media thickness) and function (assessed trough pulse wave velocity). The third objective is to analyse the effect of the intervention on biochemical markers, including glucose metabolism (blood glucose, insulin and insulin sensitivity), lipid profile (triglycerides, total cholesterol, high-density lipoprotein cholesterol and low-density lipoprotein cholesterol) and inflammation (C reactive protein). The fourth objective is to validate a submaximal exercise step test for an overweight adolescent population for future use in the PA consultation routine. Submaximal exercise step testing has been considered a timely and cost-effective[34] method of assessing CRF, which can be conducted at the clinical office with minimal risk and discomfort for the participant compared with maximal exercise testing.[35] The fifth objective is to assess the cost-effectiveness (CE) of the intervention. CE is considered an important aid to public health decision-making, with an extra potential additional value in a tertiary healthcare setting.

Participants

Participants coming from the Lisbon region, aged 12–18, with a BMI ≥p85 for gender and age,[36] attending the clinic for the first time, who agree to be enrolled, are recruited. The following are the exclusion criteria: (1) major pathologies (other than obesity or its related comorbidities), (2) inability to perform regular PA, (3) mental disorders, (4) smoking, (5) being under any kind of prescription that may interfere with body weight or (6) being involved in another weight loss and/or PA programmes (with the exception of physical education at school).

According to the sample size calculation, we are expecting to recruit 129 participants, having already started in October 2016. The eligible participants are allocated by consecutive sampling[29] into three groups: (1) control group, (2) experimental group I and (3) experimental group II. The sample size calculation was based on our primary outcome (BMI z-score). In accordance with the power analysis performed, we will need a sample size of 35 participants per group to detect a difference of ≥0.5 with a power of 0.8. Although a difference of ≥0.25 in the BMI z-score may be considered as minimal for clinical effectiveness, a difference of ≥0.5 is more consistently associated with health benefits.[37] Based on our previous experience we expect an attrition rate of about 25%, which is in line with the results reported by other authors.[38] Therefore, we aim to recruit 43 participants per group.

Experimental group I

Experimental group I participants, in addition to the standard care protocol, which includes a baseline evaluation session with a paediatrician for basal screening, followed by an appointment with a nutritionist, are exposed to a PA consultation. PA consultation consists of a patient-centred, one-to-one session based on the transtheoretical model and uses motivational interview in order to strengthen an individual's intrinsic motivation to achieve a positive PA behaviour change. In these sessions the following topics are explored: (1) explore and resolve ambivalence; (2) identify difficulties/barriers and benefits of behaviour change; (3) find the adolescent's own means and solutions for overcoming the identified barriers; and (4) enhance self-efficacy and autonomy.[23 39] In addition to behaviour change, the PA consultation aims to adjust PA and exercise (type, intensity and technique) to the individual patient clinical condition, personality and preferences.

Experimental group II

The participants allocated to experimental group II are invited to attend two physical exercise sessions per week (≈60 min/session) facilitated by one exercise physiologist. The individual's ability to exercise is assessed in order to customise the exercise plan. All the sessions include 15 min of warm-up, including 5 min of agility exercises (30%–50% heart rate reserve); 15 min of resistance training (including the major upper and lower muscles, 12–15 sets of 15 repetitions); 20 min of aerobic exercise (50%–80% heart rate reserve); and 10 min of cool-down (30%–50% heart rate reserve).[35] For all participants in the intervention group II, blood pressure pre-exercise and postexercise and the energy expenditure of each exercise session are registered. All the participants have to attend at least 80% of the scheduled sessions. The exercise sessions will take place at the nearby facilities of the Lisbon University Stadium.

Control group

The control group follows the clinic standard care protocol. The participants of the control group receive at their first visit a brochure with PA guidelines specifically directed to this age group, with examples of physical exercises.

After the first visit, appointments take place every 3 months (according to the standard care protocol) for all the three groups during 1 year. The assessments are performed at baseline and will be repeated at 6 and 12 months (follow-up) (figure 2).

Measurements

All participants undergo a variety of questionnaires (socioeconomic, self-efficacy and autonomy), anthropometric, body composition and clinical assessments, as illustrated in Figure 2. Study outcomes and instruments are described in table 1.

Statistical analysis

Statistical analysis will be performed using the IBM SPSS V.24.0 statistics software. χ^2 and one-way analysis of variance will be used to evaluate baseline differences between the control and the intervention groups. The effect of the intervention will be analysed using analysis of covariance controlling for baseline values of continuous variables. For missing data, the intention-to-treat

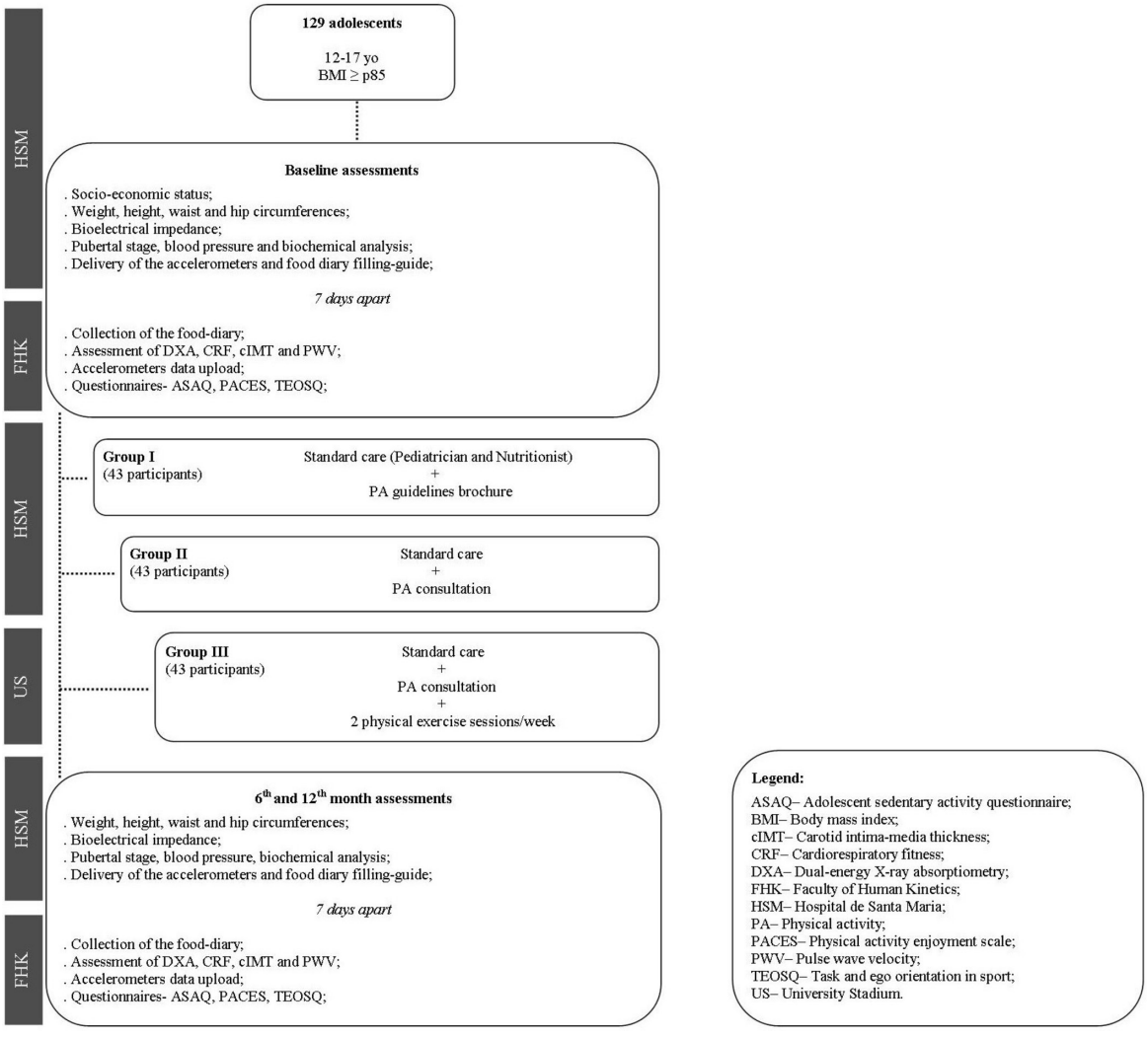

Figure 2 Participant timeline and procedures.

Table 1 Summary of study outcomes and instruments

Outcome	Instrument	Units
Socioeconomic status	Questionnaire (Portuguese National Institute of Statistics)	–
Height	Height stadiometer (SECA 217, Hamburg, Germany)	cm
Weight	Bioelectrical impedance scale (InBody 230, Seoul, Korea)	kg
BMI	(BMI=weight (kg)/height^2 (m))	kg/m^2
BMI z-score	(BMI z-score= $((BMI/M(t))^{L(t)}-1)/L(t)S(t)$)	–
Waist circumference	Circumference measuring tape (SECA 203, Hamburg, Germany)	cm
Waist for height ratio	(WHtR=waist circumference (cm)/height (cm))	–
Hip circumference	Circumference measuring tape (SECA 203, Hamburg, Germany)	cm
Body fat mass	Bioelectrical impedance scale (InBody 230)	%
Muscle mass		%
Pubertal status	Tanner's stages	–
Resting BP	Digital sphygmomanometer (CAS 9302S, CAS Medical Systems, Branford, USA)	mm Hg
Blood glucose	Hexokinase (ADVIA 2400, Siemens, Newark, Delaware, USA)	mg/dL
Blood insulin	Chemiluminescence immunoassay (ADVIA 2400, Siemens)	mg/dL
Insulin sensitivity	Homeostasis model assessment	–
Total cholesterol	Enzymatic (ADVIA 2400, Siemens)	mg/dL
HDL-C	Direct (ADVIA 2400, Siemens)	mg/dL
Triglycerides	GPO Trinder (ADVIA 2400, Siemens)	mg/dL
AST, ALT and GGT	Modified IFCC method (ADVIA 2400, Siemens)	U/L
C reactive protein	Turbidimetric immunoassay (ADVIA 2400, Siemens)	mg/L
Energy intake	3-day food diary	kcal
Physical activity	Accelerometer (ActiGraph GT3X, Pensacola, Florida, USA)	count/min
Whole body fat	DXA (Explorer W, Hologic; Waltham, Massachusetts, USA)	g
Trunk fat		g
Whole body peripheral fat		g
Trunk peripheral fat		g
Sedentary behaviours	Questionnaire (ASAQ)	min
PA enjoyment and self-efficacy	Questionnaire (PACES and TEOSQ)	–
cIMT	Ultrasound imager –13 MHz probe (MyLab One, Esaote, Genoa, Italy)	mm
PWV	Applanation tonometry (Complior, Alam Medical, Paris, France)	m/s
CRF	Cycle ergometer (Monark 839 Ergomedic, Monark, Vansbro, Sweden)	–
	Gas analyser (K4b2, Cosmed, Rome, Italy)	mL/kg/min
Resting heart rate	Digital sphygmomanometer (OMRON M3 IT, Milton Keynes, UK)	beats/min
Pre-exercise and postexercise BP		mm Hg
Exercise energy expenditure	Cardiofrequencimeter (Polar Vantage NV, Polar Electro Oy, Kempele, Finland)	kcal

ALT, alanine transaminase; ASAQ, Adolescent Sedentary Activity Questionnaire; AST, aspartate transaminase; BMI, body mass index; BP, blood pressure; cIMT, carotid intima-media thickness; CRF, cardiorespiratory fitness; DXA, dual-energy X-ray absorptiometry; GGT, Gamma-glutamyltransferase; HDL-C, high-density lipoprotein cholesterol; PA, physical activity; PACES, Physical Activity Enjoyment Scale; PWV, pulse wave velocity; TEOSQ, Task and Ego Orientation in Sport Questionnaire.

principle (last observation carried forward) will be followed.

DISCUSSION

Weight status, particularly during adolescence, is deeply influenced by biological, physiological, environmental and contextual factors.[40] According to the *Foresight Programme* of the UK Government Office for Science, published in 2007, the complex and multifactorial aetiology of overweight/obesity may involve around 108 factors and more than 300 interactions among those factors.[41] Although the *Foresight*'s map may be a good illustration of the complexity and challenge in tackling

obesity, which involves several environmental dimensions and system-wide solutions, with the individual representing only a small part, complex issues have no simple or single solutions. Without considering the individual and his role in this complex system, we may fail in inducing successful changes.

According to Bemelmans *et al*,[42] several community-based initiatives for the management of childhood/adolescent overweight, implemented between 2005 and 2011, have shown confounding results on BMI. These confounding results may be explained by the inconsistent use of behaviour change strategies across studies. Behaviour is a key factor for most health outcomes, including weight.[43] Adolescence is a critical period for the acquisition of healthy behaviours.[18] Being able to positively and effectively influence health behaviours during this time period may prevent future individual health adversities. This trial aims to analyse the impact of a behavioural change intervention (with or without the participation in scheduled physical exercise sessions) on PA behaviour and on a range of biomarkers, while trying to understand whether and how health behaviours have the potential to be modified at the clinical setting.

Environmental changes, although crucial for the future, take time to produce physiological effects. Thus, this trial should be considered as a contribution to tackling adolescent overweight at the individual level. To the best of our knowledge there have been no controlled trials with this dimension which have analysed the impact of a PA consultation on the management of adolescent overweight. In our view, among the strengths of this trial is its focus on the enhancement of intrinsic motivation, individual autonomy and self-efficacy, which are known to be key aspects of behaviour change and successful weight loss.[27] The individual physical exercise sessions that will be provided to one-third of the participants aim to increase self-efficacy perception associated with weight loss, and to understand whether this perception influences autonomy and maintains PA behaviour in the long run. We believe that this clinical trial will contribute to the improvement in the management of adolescent overweight at the clinical setting, and may simultaneously provide a better understanding of the behavioural mechanisms involved in the process of losing weight and maintaining weight loss during this critical life stage.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Research ethics committee of the Faculty of Medicine, University of Lisbon, Lisbon, Portugal (271/2016).

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