

Statistical Analysis Plan (SAP)* Version 1

Date: March 2nd 2020

Running title:

Fitness for all: Adult people with physical disability in Denmark - Prevalence and social markers

Content:

SECTION 1: Administrative information	2
SECTION 2: Introduction	3
SECTION 3: Study methods.....	4
SECTION 4: Statistical methods	5
SECTION 5: Study population	5
SECTION 6: Analysis	7
References:.....	8

*THIS SAP is structured and inspired by the guideline for SAP for clinical trials by Gamble et al [1].

SECTION 1: Administrative information

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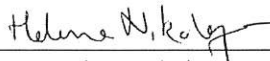
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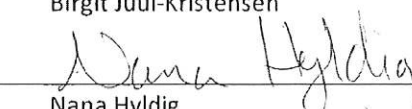
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SECTION 2: Introduction

Background and rationale for the study:

"Fitness for all" aims to make fitness centres more accessible and usable for people with physical disability and is focusing on building/rebuild and adjust 3 specific locations with non-profit fitness centres in relation to sports clubs. This project is a cross sectional descriptive study, based on data from the Danish National Patient Register (DNPT), (in Danish: Landspatientregistret (LPR)) and Statistics Denmark, focusing on identifying and describing the group of potential disabled fitness centre users in Denmark. Characteristics of the group are based on specific diagnoses combined with demographic and socioeconomical variables.

Physical inactivity poses threat to public health, causes morbidity and mortality and is a major economic burden [2,3]. Globally 23% of the adult population does not reach the general recommendations of physical activity [4]. In 2016 the prevalence of people with physical inactivity was more than twice as high in high-income countries as in low-income countries and insufficient activity has increased in high-income countries over time [5]. For the Western societies the number of sedentary people is as high as 63% of the men and 75% of the women in UK [3]. WHO recommends adults to perform at least 150 minutes of at least moderate physical activity each week, or a minimum of 75 minutes of vigorous activity per week or an equivalent combination of moderate and vigorous activity [6]. This recommendation both holds for adults with and without physical disabilities but may be of greater concern for people with disabilities as they generally tend to be more physically inactive [7]. Furthermore, they experience more chronic diseases and conditions, which typically occurs at earlier ages than people without physical disabilities [8].

Physical activity may increase by using the growing fitness centre industry, which by some is considered the world's biggest "sport" [9]. Fitness centre training has increased in popularity since the 1970's [10] but is often not a possibility for people with disability due to accessibility issues [11–14]. In some parts of the world, mainly USA and UK, focus is on how to overcome all these barriers and how to make fitness centres accessible and usable for people with disability [15–18]. In Western societies such as Denmark it is still a very unexplored area. Therefore, basic information and characteristics of this target group of people with physical disability are essential when aiming to make fitness centers accessible and usable for this group. Further, increasing physical activity can reduce the risk of lifestyle diseases and maintain physical abilities and independence throughout the lifespan for this group. Such new knowledge may lead to changes of how to build and use fitness centres, organise the training and develop an inspiring atmosphere to increase the number of people exercising in fitness centres.

Aims:

To identify and describe the group of potential fitness participants with disabilities in Denmark in terms of demographic and socioeconomic variables.

Objectives:

- 1) Determine the prevalence of the whole group of people with physical disability, distributed by eight diagnosis-based subgroups in Denmark.
- 2) Describe the demographic and socioeconomic variables (marital status, origin, education level, occupation etc.) for the eight subgroups of people with disability.

SECTION 3: Study methods

Trial design:

A cross-sectional descriptive study, reporting data available at December 31st 2018 from the Danish National Patient Register (DNPT) and Statistics Denmark. The STROBE guideline [19] will be followed when reporting. This Statistical Analysis Plan will be made publicly available at PURE.

The population will be defined by the research group and data extraction will be performed by Statistics Denmark (see section 5), including the following basic demographic variables from Statistics Denmark:

(See code book for detailed information of the variables.)

BEF - Befolkningen (år)

BEF	Beskrivelse/Description	English translation	År/year
PNR	Recordnummer (pseudonomiseret)	Record number	2018
FOED_DAG	Fødselsdag	Date of birth	2018
KOEN	Køn	Sex	2018
REG	Region	Region of Denmark	2018
KOM	Kommunekode	Municipality	2018
CIVST	Civilstand	Marital status	2018
IE_TYPE	Indvandrere, efterkommere, personer med dansk oprindelse	Origin	2018

UDDF - Højeste fuldførte uddannelse (forløb)

UDDF	Beskrivelse/Description	English translation	År/year
PNR	Recordnummer (pseudonomiseret)	Record number	2018
HFAUDD	Højeste fuldførte uddannelse	Highest level of education	2018

AKM - Arbejdsklassifikationsmodul

AKM	Beskrivelse/Description	English translation	År/year
PNR	Recordnummer (pseudonomiseret)	Record number	2018
SOCIO13	Socioøkonomisk klassifikation version 2013	Socioeconomic classification, version 2013	2018

HANDIC - Handicapydelse

HANDIC	Beskrivelse/Description	English translation	År/year
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PNR	Recordnummer (pseudonomiseret)	Record number	2018
FUNK_VURD	Samlet funktionsvurdering	Overall functional assessment	2018

SECTION 4: Statistical methods

Descriptive statistic will be performed with the overall focus of determining the prevalence among the whole group of people with disability in Denmark distributed by the eight subgroups. The denominator will be the total population in Denmark at December 31st 2018 within the age range as reported by Statistics Denmark (<https://www.dst.dk/en/Statistik/statistikbanken>).

Descriptive measures such as numbers, frequencies (%), means (95% confidence intervals) and/or medians (SD) will be presented.

SECTION 5: Study population

The study population, adults (18 years or older) with physical disability is defined by 8 diagnosis groups/cluster of diseases, (See table 1) identified in the Danish National Patient Register, a government-funded population-based administrative registry which is collecting data from all Danish hospitals [20].

The study population is created by Statistics Denmark, from the following criteria:

All persons from The Danish National Patient Register (DNPR), who in the period from 1994 and onwards, were given one or several of the following ICD-10 codes (including both A and B diagnoses in all finished/completed procedures). Further, the persons have to be alive and be living in Denmark on December 31st 2018.

Table 1. Population by ICD-10 codes. * indicates all sub codes are included.

	Sygdom/Disease	English translation	ICD-10 codes	Codename in the Danish ICD-10 system
1	Cerebral Parese	Cerebral Palsy	G80*	Cerebral parese
2	Erhvervet hjerneskade (apoplexi + traume)	Acquired brain injury apoplexia traumatic	I61* I63* I64* I691 I693 I694 S020* S021* S027*	Hjerneblødning Hjerneinfarkt Slagtilfælde uden oplysning om blødning eller infarkt Senfølge efter tidligere hjerneblødning Senfølge efter tidligere hjerneinfarkt Senfølge efter tidligere apoplexia cerebri

			S028* S029* S061 S062* S063* S064* S065* S066 S067 S068* S069 S070 S071 S079 T020 T040 T060	Fractura thecae cranii Fractura baseos cranii Fractura multiplex cranii eet ossis faciei Kraniebrud og brud af ansigtets knogler, andre former Kraniebrud og brud af ansigtets knogler uden specifikation Oedema cerebri traumaticum Laesio traumatica cerebri duffusa Laesio traumatica cerebri focalis Haemorrhagia epiduralis traumatica Haemorrhagia subduralis traumatica Haemorrhagia subarachnoidalis traumatica Laesio traumatica intracranialis m protraheret coma Interkranielle læsioner, andre Interkranielle læsioner uden specifikation Conquassatio faciei Conquassatio cranii Laesio traumatica multiplex capitis Frakturer både på hoved og hals Conquassatio både hoved og hals Læsion af hjerne hjernenerver med spin el. nerver på hals
3	Gigttilidelser (Reumatoid Artrit + Slidgigt)	Rheumatic diseases (RA + some OA)	M05* M06* M16* M17* M19*	Seropositiv leddegigt andre former for leddegigt Slidgigt i hofte Slidgigt i knæ Andre former for slidgigt
4	Muskelsvindsygdomme	Muscular dystrophy	G71*	Primære muskelsygdomme
5	Rygmarvsskadede incl. spina bifida	Spinal cord injuries incl, spine bifida	G82* M471C T144C T144D G114 Q05* Q760	Paraplegi og tetraplegi Spondylose i halshvirvelsøjlen med myelopati og tetraplegi Traumatisk paraplegi UNS Traumatisk tetraplegi UNS Arvelig spastisk paraplegi Spina bifida Spina bifida occulta

6	Sklerose	<u>Multiple Sclerosis</u>	G35*	Dissemineret sklerose
7	Polio (alle stadier)	Poliomyelitis (all stages)	A80* B91 G14*	Akut polio Følger efter polio Postpoliosyndrom
8	Amputation – OE & UE minus finger og tæer	Amputations (UE & LE except fingers and toes)	S48* S58* S68 S684 S688 S689 S78* S88* S98 S983 S984 T05* T116 T136 T926 T936	Traumatisk amputation af skulder og overarm Traumatisk amputation af albue og underarm Traumatisk amputation af håndled og hånd Traumatisk amputation af hånd Traumatisk amputation af anden del af håndled eller hånd Traumatisk amputation af håndled eller hånd UNS Traumatisk amputation af hoft og lår Traumatisk amputation i knæregion eller underben Traumatisk amputation af ankel og fod Traumatisk amputation af anden del af fod Traumatisk amputation af fod UNS Traumatisk amputation af flere legemsdele Traumatisk amputation på arm UNS Traumatisk amputation på ben UNS Følgetilstand efter knusningslæsion eller traumatisk amputation på overekstremitet Følgetilstand efter knusningslæsion eller traumatisk amputation på underekstremitet

SECTION 6: Analysis

Analysis methods: descriptive statistics (see section 4)

Statistical software

Data is accessed via a connection to research servers at Statistics Denmark. Further, the software STATA will be used to access, manage, analyse and present data.

Presentation:

Data will be presented in tables and illustrated with figures where appropriate. If certain cell sizes are too small to comply with data protection regulations, data will be collapsed or blurred before publication.

The Basic demographic characteristics: (see also section 3 and the code book)

Gender (binominal)

Age (ratio-interval)

Region in Denmark (nominal)

Highest education level (ordinal)

Occupation (nominal)

Marital status (nominal)

Origin (nominal)

Functional level (ordinal) (may not be usable, it is voluntary for the municipalities to report it)

References:

- [1] Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Doré C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. *JAMA* 2017;318:2337. <https://doi.org/10.1001/jama.2017.18556>.
- [2] Ding D, Lawson KD, Kolbe-Alexander TL, Finkelstein EA, Katzmarzyk PT, van Mechelen W, et al. The economic burden of physical inactivity: a global analysis of major non-communicable diseases. *The Lancet* 2016;388:1311–24. [https://doi.org/10.1016/S0140-6736\(16\)30383-X](https://doi.org/10.1016/S0140-6736(16)30383-X).
- [3] Allender S, Foster C, Scarborough P, Rayner M. The burden of physical activity-related ill health in the UK. *Journal of Epidemiology & Community Health* 2007;61:344–8. <https://doi.org/10.1136/jech.2006.050807>.
- [4] World Health Organization. 10 facts on physical activity. World Health Organization 2017. http://www.who.int/features/factfiles/physical_activity/en/ (accessed July 30, 2018).
- [5] Guthold R, Stevens GA, Riley LM, Bull FC. Worldwide trends in insufficient physical activity from 2001 to 2016: a pooled analysis of 358 population-based surveys with 1.9 million participants. *The Lancet Global Health* 2018;6:e1077–86. [https://doi.org/10.1016/S2214-109X\(18\)30357-7](https://doi.org/10.1016/S2214-109X(18)30357-7).
- [6] World Health Organization. Global recommendations on physical activity for health. World Health Organization (WHO); 2010.
- [7] Carroll DD, Courtney-Long EA, Stevens AC, Sloan ML, Lullo C, Visser SN, et al. Vital

Signs: Disability and Physical Activity – United States, 2009-2012 2014;63:7.

[8] Krahn GL, Walker DK, Correa-De-Araujo R. Persons With Disabilities as an Unrecognized Health Disparity Population. *American Journal of Public Health* 2015;105:198–206. <https://doi.org/10.2105/AJPH.2014.302182>.

[9] Burgess T. Fitness is the world's biggest sport 2013.

[10] Sassatelli R. Fitness Culture. *Gyms and the Commercialisation of Discipline and Fun*. 2014.

[11] Rimmer JH. The Conspicuous Absence of People with Disabilities in Public Fitness and Recreation Facilities: Lack of Interest or Lack of Access? *American Journal of Health Promotion* 2005;19:327–9. <https://doi.org/10.4278/0890-1171-19.5.327>.

[12] Rimmer JH, Padalabalanarayanan S, Malone LA, Mehta T. Fitness facilities still lack accessibility for people with disabilities. *Disability and Health Journal* 2017;10:214–21. <https://doi.org/10.1016/j.dhjo.2016.12.011>.

[13] Gross J, Kroll T, Morris J. Accessibility of fitness centres for people with disabilities in a region in North East Scotland. *Public Health* 2013;127:782–4. <https://doi.org/10.1016/j.puhe.2013.04.030>.

[14] Calder A, Sole G, Mulligan H. The accessibility of fitness centers for people with disabilities: A systematic review. *Disability and Health Journal* 2018;11:525–36. <https://doi.org/10.1016/j.dhjo.2018.04.002>.

[15] Inclusive Fitness Coalition. *Facts for Fitness Centers Information Sheet: Making Your Health & Fitness Center a Welcoming Facility* 2015.

[16] North Carolina Office on Disability and Health, in collaboration with, The Center for Universal Design. *Removing barriers to Health Clubs and Fitness Facilities - A guide for Accommodating All Members, Including People with Disabilities and Older Adults*. The University of North Carolina; 2008.

[17] Inclusive Fitness Coalition. *Inclusion and Adaptation* n.d.

[18] Activity Alliance. *Inclusive Fitness Initiative* 2020. <http://www.activityalliance.org.uk/how-we-help/programmes/65-inclusive-fitness-initiative> (accessed January 30, 2020).

[19] Vandembroucke JP. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. *Annals of Internal Medicine* 2007;147:W. <https://doi.org/10.7326/0003-4819-147-8-200710160-00010-w1>.

[20] Schmidt M, Schmidt SAJ, Sandegaard JL, Ehrenstein V, Pedersen L, Sørensen HT. The Danish National Patient Registry: a review of content, data quality, and research potential. *Clinical Epidemiology* 2015;449. <https://doi.org/10.2147/CLEP.S91125>.