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Inertial sensors versus standard systems in gait analysis: a systematic review and meta-analysis

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TITLE: **Inertial sensors versus standard systems in gait analysis: a systematic review and meta-analysis.**

RUNNING TITLE: Gait analysis using inertial sensors.

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Abstract

INTRODUCTION: The increasing popularity of inertial sensors in clinical practice is not supported by precise information on their reliability or guidelines for their use in rehabilitation. The authors investigated the state of the literature concerning the use of inertial sensors for gait analysis in both healthy and pathological adults comparing traditional systems. Furthermore, trying to define directions for clinicians.

EVIDENCE ACQUISITION: in accordance with the PRISMA statement, authors searched in PubMed, Web of Science and Scopus all paper published from January 1st, 2005 until December 31st, 2017. They included both healthy and pathological adults' subjects as population, wearable or inertial sensors used for gait analysis and compared with classical gait analysis performed in a Motion Lab as intervention and comparison, gait parameters as outcomes. Considering the methodological quality, authors focused on: sample; description of the study; type of gait analysis used for comparison; type of sensor; sensor placement on the body; gait task requested.

EVIDENCE SYNTHESIS: From a total of 888 articles, 16 manuscripts were selected and 7 of them were considered for meta-analysis for different gait parameters. Demographic data, tested devices, reference systems, test procedures and outcomes were analyzed.

CONCLUSIONS: Our results show a good agreement between inertial sensors and classical gait analysis for some gait parameters, supporting their use as a solution for capturing kinematic information over an extended space and time and even outside a laboratory in real-life conditions. Authors can support the use of portable inertial sensors for a practical gait analysis in clinical setting with good reliability. It will then be the experience of the clinician to direct the decision-making process.

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Text

Introduction

The analysis of human motion is an interesting issue and of increasingly interest in rehabilitation. Gait analysis provides kinetic and kinematic data (information) on functional motor aspects of subjects[1–4] that could be used to define therapeutic intervention and outcome evaluation. Even for the World Health Organization, as described in the ICF (International Classification of Functioning, Disability and Health), the Functional capabilities such as activity level and participation are recognized as crucial in clinical evaluation[5] and could be very interesting in rehabilitation.[6] Nevertheless, the available literature is often difficult to apply to clinical practice and it is necessary to deepen the research trying to obtain comparable results, as also stated by the Italian Society of Clinical Movement Analysis.[7]

The gold standard for gait analysis is represented by optoelectronic systems that use motion capture techniques, force platforms and EMGs electrodes. These devices allow to measure the dynamic neuromuscular pattern (multichannel EMG), the global and segmentary kinematic characteristics (3D analysis systems), the global and segmentary kinetic characteristics (dynamomentric platforms) and sometimes the energy expenditure of walking (oxygen consumption measurement systems). [8–11]

The typical instrumental equipment of a motion analysis laboratory comports high costs in terms of spaces settings and timing for the patient preparation (undressing, skin preparation, markers positioning on suitable reference points according to defined protocols).[8]

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In order to obtain an objective assessment of health-related outcomes in real-life settings, according to new trends,[12] various sensors and sensor combinations have been used to analyze gait in ambulatory settings.[13] This need has prompted researchers to develop inexpensive, little, lightweight and portable devices named Inertial Sensors (IS). These devices are able to assess movements by measuring the inertia of a suspended mass. Thanks to the rapid progresses in the Micro Electro-Mechanical Systems (MEMS) field, mm-sized devices can be fabricated, that provide accurate and reliable measurements. Those devices often include an integrated circuit (IC) interface consisting of an analog signal-conditioning block, for amplification and filtering of the recorded signal, and an analog-to-digital interface for digitalizing the acquired data. Different measuring principles are available (piezoelectric, piezoresistive), but currently most commercial accelerometers rely on capacitive measurements to convert the displacement into an electric signal.[14] Capacitive accelerometers have very low power requirements and are therefore ideal for development of wearable, wireless and battery-powered devices.

These are all major assets when the transfer of power and data to the transducer is challenging, and a wired link does not offer a viable long-term solution, like in medical implants or wearable devices. Opportunely packaged MEMS accelerometers can be used for monitoring heart motion[15] or bladder movements.[16] Wearable accelerometers can be used to measure heart rate,[17] breathing,[18] pathological tremors,[19] or in general to assess physical activity.[20] Several wearable accelerometers have also been developed over the years[21] for gait analysis.[22,23]

Linear acceleration sensors are exclusively able to measure the acceleration along a specific direction. Depending on the number of sensitive directions, these transducers can be classified in one- two- and three-axis accelerometer. When information on rotation of

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the device is required, as in gait analysis, angular velocity sensors (gyroscopes) have to be added. Low-cost gyroscopes are still subject to bias, scale factors and other random errors, and therefore require regular calibrations.[24] An assembly of a three-axis gyroscope and a three-axis accelerometer is called an Inertial Measurement Unit (IMU).[21] Gyroscopes compute the angular displacement of the device by numerical integration of the angular velocity data. Small measurement error in velocity accumulate over time and result in progressively increasing errors in the computed displacement. This is known as integration drift. A magnetometer, measuring the earth's magnetic field orientation, is often added to the sensor assembly to allow for easier re-calibration of the device and to compensate for gyroscope drift issues. In this case the devices are referred to as MIMUs (Magnetic-Inertial measurement units, from now on, we will generically refer to IS, IMU and MIMU as "IMUs").[25,26] IMUs have been used since the seventies[27] but thanks to the recent progresses in MEMS technology, that significantly improved gyroscopes performance,[28,29] currently they are the most commonly used wearable devices for gait analysis.[30] Methodological approaches used for estimating lower limb joint kinematics[29] and biomechanical elements for gait analysis with accelerometers have been described.[31,32] The latest ones use wireless technology and can be employed in a variety of ways. Some can be inserted into the shoes,[33–35] some can be placed on the arm,[36] on the lower limb,[37,38] on the trunk,[39,40] on the lumbar region[41] or even integrated in smart device like iPod Touch.[42] Others could be applied directly to the joints, or indirectly estimate the joint center of rotation.[43] They are used in motion analysis to obtain different kinetic and kinematics variables and related parameters,[44–46] in particular joint kinematics. The latter is considered a key descriptor to differentiate pathological from normal gait.[47,48] Commercially available solutions usually returns an estimation of 3D

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joint kinematics, but they could have issues related to ferromagnetic disturbances that could be present in ambulatory settings. even if there are some algorithms effective in compensating those disturbances.[29,49–51] Large iron objects in close proximity to the sensors, and varying electric fields, can induce a significative error in orientation measurement (>30°).[52] Palermo et al demonstrated that in a motion analysis lab this distortion is limited to the transverse plane of each joint and the frontal plane of the ankle, while the measurements of the sagittal plane are the least affected.[53]

A robust and precise placement of the device on specific anatomical positions is a basic requirement for a reliable and repeatable measurement,[54,55] and body-to-sensor calibration procedures have been proposed to obtain more robust results in respect to different sensor positions on the body.[56]

The accuracy of assessments also depends on several other factors such as the exact measurement of distance walked, the instructions given to the subject, the algorithm used, the precision of gait event identification (that could be tricky in pathological gait), the reference gait database used[57,58] and a spot check that allows the users to be aware of the errors.[59] Furthermore, a thorough comparative analysis of methods with regards to number of extra and missed events, accuracy and robustness to IMUs location is still lacking in the literature.[60] Dejnabadi and colleagues developed a model based on estimating acceleration of the knee joint center of rotation using virtual sensors mathematically shifting the location of the physical sensors. In this study, the absolute joint angle was found to be unaffected from any source of drift.[61] Literature shows that several methods have been used to minimize the influence of gravitational acceleration on inertial sensors outputs, but it is unclear whether differences in the used methods would yield different results and potentially influence the results of different studies.[62]

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The main complication in the uniaxial assessment of lower limb kinematics is the large numbers of sensors required for a complete spatial-temporal analysis. Instead of measuring the joint angles directly, Hu and co-author used the inertial sensors to obtain critical relative limb motions and estimate the joint angles in an indirect way combining the information collected by four different sensors. The joint angles estimates were only affected by small errors within an acceptable range.[63] For a complete assessment of lower limb kinematic it is important to obtain the hip, knee and ankle joint parameters simultaneously, but a large numbers of inertial sensors increases the complexity of the measurement. Some authors used a simplified planar gait model using inverse kinematics with a reduced numbers of IMUs and they obtained an accurate result. However a little error is consequent to a small displacement of the lower limbs in the mediolateral direction due to the pelvis rotation. In reality, the thigh and shank lengths are slightly different because of this mechanism.[64] Some authors supposed that the drift inherent to the accelerometer signals is often reduced by exploiting the cyclical nature of gait and under the hypothesis that the velocity of the sensor is zero at some point in stance, but only if the sensor is attached to the foot.[65]

Moderate to poor agreement has been reported for step-to-step fluctuations (variability) and bilateral coordination (asymmetry), excellent agreement with a laboratory reference system has been reported for mean gait characteristics.[66–68] Authors interpreted those results as related to limited and inconsistent reporting of gait characteristics in literature (e.g. restricted testing on small cohorts of patients) and to an intrinsic limitation of the comparison between the two systems, which measures different properties (e.g. continuous motion versus single footfall events).[69]

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Concerning pathological gait, it is particularly difficult to evaluate the gait in hip osteoarthritic patients because their pelvic movements display abnormal pattern even before clinical symptoms,[70] but inertial sensors assessment seems to be useful to assess changes in physical activity after total hip or knee arthroplasty.[71] Different algorithms have been validated to assess gait kinematics in chronic disease,[72] in normal and clinically impaired gait[73] during walking and running on supports such as a treadmill[74,75] at different speeds. IMUs have been used in neurological population,[76,77] as well as in stroke survivors,[78] in multiple sclerosis,[79,80] in spinal-cord injuries,[81] in cerebellar ataxia[82] or in patients with drop foot,[38,83] even for complex regional pain syndrome[84] or in spinal pathologies.[85] In a recent paper Del Din et al.[69] states that a three-axis accelerometer is able to adequately measure some parameters compared with a laboratory reference system with agreement from excellent to poor in Parkinson's disease and in healthy older adults. IMUs may be promising in Parkinson's disease even for the diagnosis, for a continuous monitoring of daily activities, for the progression tracking,[86] and to detect gait disturbance such as freezing of gait and risk of falls, despite further work in ecological validation are necessary.[87] In some kind of pathologies, however, these devices are not yet reliable and they require more specific validation in target clinical populations (e.g. rheumatoid arthritis).[88] Controversial results are available for amputees, because calculation of step length data is generally obtained by dividing stride length by a factor of two and this means that patients walk symmetrically. This is not true in amputees subjects, were typical gait pattern is characterized by reduced angular motion of the tibialis segment.[89,90] To our knowledge, the usability of IMUs in lower limb prosthesis has been reported in two studies.[91,92]

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The growing interest in objective measurements that allow cross-platform comparison of results, has led to formulate recommendations for assessing the validity of sensor-based activity monitoring in older persons with focus on the measurement of body postures and movements.[93] Even the European GAITRite network group recommends guidelines to enhance reproducibility of gait measures and for better comparability of clinical outcomes in the elderly. An example is the highest possible number of gait cycles from a practical standpoint with a minimum of 12 consecutive steps to evaluate stride time variability.[94] Physical activity assessment is very important for physicians, not only it is a significant measurement outcome, it can also be a therapeutic intervention on its own, especially in rehabilitation. However, it is difficult to obtain an objective measure of physical activity in community dwelling populations. IMUs devices are a promising tool to overcome this limitation.[95] IMUs have been used to evaluate physical activity[96] in a range of activities like sitting, lying, walking and standing in controlled and home settings in elderly.[97] Despite slow gait speed of older people may result in misclassification of walking or underestimation of step count[98], and despite an error up to 25% in discriminating sitting from standing,[97] IMUs are a valuable measuring instrument for the elderly who are easily fatigued and do not easily tolerate the long measurement times required by the gold standard. Furthermore gait impairment is closely related to cognitive degeneration[99] and an objective measurement of spatial-temporal gait parameters may detect possible gait disturbances and quantify the effects of therapeutic interventions with a good test-retest reliability.[100] Gait speed has been reported to be a relevant marker of health, well-being and functional status of older population.[101] IMUs can be used to assess foot clearance to understand the relationship between gait and falls[102,103] and to assess gait stability.[46] The objective information provided by IMUs are

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potentially more valid and reliable than the current standard assessment of walking time with a stopwatch in older individuals and may theoretically identify deteriorating gait and disability.[104] Studies comparing the instrumental and non-instrumental evaluation of gait in elderly shows that the concordance of two tests is not optimal and manual measures might lead to misclassification of subjects.[105]

The IMUs can be a solution for capturing kinematic information over an extended space and time and even outside a laboratory in real-life conditions.[40,106] Despite all described issues and concerns, several studies have assessed the validity of different ambulatory activity monitors by comparing their outputs with other kind of measures like optometric systems, treadmill, observers, clinical test and other IMUs.[107–109] They could be an alternative to classical gait analysis or to visual observation that provides qualitative and unreliable results even difficult to compare across multiple visits and different clinicians.[44,110] IMUs can be used in both clinical practice and scientific research, however effectiveness, accuracy, reliability and sensitivity of this kind of assessment is still much debated especially in pathological pattern of gait.[111,112] Nevertheless, a recent review shows encouraging results for the application of adaptive algorithms on IMU-based data to support clinical evaluation.[113] Consensus on validity testing in motion analysis recommends that validity and reliability of IMUs should be demonstrated in the condition in which it is to be used.[93] The aim of this study is to investigate the state of the literature concerning the use of inertial sensors for gait analysis in both healthy and pathological adults comparing traditional systems. Furthermore, our objective is trying to define directions for clinicians.

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Evidence acquisition

This systematic review was conducted and reported in accordance with the PRISMA statement.[114]

Databases and search strategy

We searched all paper published from January 1st, 2005 until December 31st, 2017 in the following electronic databases: PubMed, Web of Science and Scopus, whereas in the Cochrane library a search was performed only within the keywords of the articles. Book chapters, review papers, and conference abstracts were evaluated. The search query, based on the PICO strategy, included both healthy and pathological adults' subjects as population, wearable or inertial sensors used for gait analysis and compared with classical gait analysis performed in a Motion Lab as intervention and comparison, as outcomes gait analysis. However, singular spatio-temporal and kinematics parameters were not included in the search strategy to keep a broad query.

The string "((((((accelerometry[MeSH Terms]) OR actigraphy[MeSH Terms])) OR ("inertial sensor*" [tiab] OR accelerometer* [tiab]))) AND gait [tiab]) AND valid* [tiab]" used for Pubmed and adapted for the other databases, was launched in the first week of January 2018 and contained at least two of these terms: "accelerometry", "acceleration", "accelerometer", "accelerometer*", "actigraphy", "inertial sensor*", "validation" and "validat*". Those keywords were used in several combinations with Boolean operators (AND/OR) and modified for databases. Given the extensive available literature on the subject and the lack of uniformity in the terminology adopted, it was decided to use in the search string some generic terms (e.g. gait) to avoid losing potentially interesting manuscripts.

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Selection criteria

In order to find the most relevant studies we included articles that met the following inclusion criteria:

- written in English
- studies conducted on human adults subjects (more than 18 years)
- both healthy subjects and pathological patients
- comparison with classical gait analysis in a motion Lab (optoelectronic, instrumented walkway)

Exclusion criteria were as follow:

- not case report or case series
- no smartphone, step counters, pedometers or similar devices used as inertial sensors
- data not compared with classical gait analysis performed in a Motion Lab, but compared with experimental devices
- no studies with walking test conducted on treadmill or other similar devices

Data extraction

Articles were initially screened by title and abstract. Articles unclear from their title or abstract were reviewed according the selection criteria trough full-text. Two authors (P.F., S.L.) independently extracted data from the studies that met the inclusion criteria and they were blinded to each other's. Considering the methodological quality, the two reviewers focused on the following topics: sample; description of the study; type of gait analysis used for comparison; type of sensor; sensor placement on the body; gait task requested. In case of disagreement, a third opinion was sought (C.C.).

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Assessment of Risk of Bias

The level of evidence of included studies was stratified according to the Oxford Center for Evidence-Based Medicine (OCEBM).[115] Two authors (S.L., P.F.) independently assessed methodological quality of data acquisition using the Critical Appraisal Skills Programme for Diagnostic Test Studies (CASP).[116] In the case of three possible response ('yes', 'no' o 'can't tell'), were one author entered 'no' often the other entered 'can't tell', although both responses scored 0. In case of disagreement, a third opinion was sought (C.C.). As this review combines the fields of engineering and medicine, both quality assessment tools are not used as exclusion criteria, but only to objectively compare between reviewers the different publications examined.

Statistical Analysis

A Random Effects model was used to calculate the pooled estimates with 95% confidence intervals for each of the meta-analysis. Standardized Mean Difference [SMD] was used as a measure of effect size. Heterogeneity was assessed by using the Q statistic and I^2, which is the proportion of total variance observed between the studies attributed to the differences between studies rather than to sampling error. $I^2<25\%$ was considered as low in heterogeneity and $I^2>75\%$ as high in heterogeneity. Possible publication bias was assessed using a contour-enhanced funnel plot of each study's effect size against its standard error. Funnel plot asymmetry was evaluated by Begg and Egger tests (not shown). All statistical analyses and forest plots were produced using the open source

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statistical system Jamovi v. 0.9.1.7[117] with the additional package "MAJOR". Jamovi is based on the widespread open statistical system R[118] and "MAJOR" is based on the R package "Metafor()". Random Effect variance , τ^2 , was obtained by Restricted Maximum Likelihood Estimation

Evidence synthesis

Overview of the inclusion process

Querying PubMed, Scopus and Web of Science, databases resulted respectively in 222, 286 and 380 papers matching the search criteria. Book chapters, review papers, and conference abstracts were excluded when deemed not suitable because of limited body of data neither related to the study nor comparison design. From a total of 888 articles, 472 duplicates were excluded. The selection process (Figure 1) generated 16 manuscripts, and 7 of them were considered for meta-analysis. The level of evidence of the included articles, according to the OCEBM Level of Evidence[115] is II.

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[PLACE HERE FIGURE 1]
Figure 1.- Flow chart of the study

Demographic Data

Five hundred thirty-eight subjects between 22 and 82 years old (240 Males and 200 Females can be certainly noticed as three authors[119–121] did not provide the exact count) were examined.

A total of 341 healthy people underwent the test, 126 young and 215 elderly. Unhealthy people were 177: 76 with Parkinson's disease,[69,112,121–124] 26 with unilateral hip Osteoarthritis,[125] 45 patients with hemiparesis,[112,122,126] 20 with Huntington's Disease,[112,122] 8 with cerebellar ataxia SCA14 type[82] and 22 with cerebellar ataxia type SCA6.[127] In 7 articles[69,82,112,122–124,127] both healthy and patients has been considered.

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Table I.-Summary of demographic characteristics.

	Age	Healthy subjects	Patologic subjects
Buganè 2012[41]	25,9±2,64	22	
Godfrey 2015[119]	28,62±5,33	40	
	63,78±6,5	37	
Hartmann 2009[128]	77,2±4,7	23	
Lord 2008[123]	70,5±3,3		12, Parkinson's Disease
	73 ±3,3	11	
Byun 2016[100]	68.67±6,14	82	
Del Din 2016[69]	66,9±9,4		30, Parkinson's Disease
	66,6±7,7	30	
Kluge 2017[124]	33,6±5,7	11	
	70,5±6,6		4, Parkinson's Disease
Köse 2012[120]	31±6	9	
Trojaniello 2015[122]	69,7± 5,8	10	
	58,6±12,1		10, Hemiparetic
	73,8±5,7		10, Parkinson's Disease
	50,3±13,3		10, Huntington's desease
Trojaniello 2014[112]	69,7± 5,8	10	
	58,6±12,1		10, Hemiparetic
	73,8±5,7		10, Parkinson's Disease
	50,3±13,3		10, Huntington's desease
Item-Glatthorn 2012[125]	54±9		26, Unilateral hip Osteoarthrosis
Esser 2012[121]	59.7±11,7		10, Parkinson's Disease
Godfrey 2014[129]	32,5±4,8	12	
	65.0±8,8	12	
Schmitz-Hübsch 2016[82]	50 (30-62)	9	
	53 (29-70)		8, Cerebellar ataxia, SCA14
Moore 2017[126]	63±11		25, Post-stroke patients
Hickey 2016[127]	57,18		22, Cerebellar ataxia, SCA6
	51,30±12,31	23	

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Tested Devices

The tested devices can be grouped into 2 categories: devices made by a single Inertial Measurement Unit (IMU) which contains different sensors, and systems made of a variable number of sensors placed in various positions on the subject body. Eleven of selected articles used a single IMU:

-8 of them[41,69,100,119,126–129] contained a 3-axial accelerometer;

-one paper[120] used a single 3-axial accelerometer and two 2-axial gyroscopes;

-another one[122] used a single 3-axial accelerometer and a 3-axial gyroscope;

-Esser et al.[121] used a 3-axial accelerometer together with a 3-axial magnetometer and 3 gyroscopes;

-two authors[112,124] used a system of 2 IMU each containing a 3-axial accelerometer and a 3-axial gyroscope;

-two authors[123,125] used systems made of five bi-axial accelerometers;

-Schmitz-Hübsch et al.[82] used a system of six body-worn wireless sensors: although the name and the sampling rate of the device are reported, the authors did not provide others technical specifications.

All the tested devices were equipped with batteries and control-chip boards and did not require a wired link to communicate with computer during the tests execution. In particular 11 authors used devices that record data with on-board memory chip ("data log" mode). Data were downloaded to a computer using a cable, a memory card adapter or a Bluetooth trans-receiver.[124] Some authors[112,120–123] did not provide any information

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about the data exchange method. Trojaniello et al.[122] declared only that a custom-made cable has been used to synchronize the IMU and the instrumented walkway.

Only Item-Glatthorn et al.[125] and Schmitz-Hübsch et al.[82] declared the use of proprietary software provided by the manufacturer of the IMU and designed with the purpose of gait analysis. The other Authors acquired the devices' raw acceleration signals using their custom-made software such as MATLAB scripts (The MathWorks Inc., Natick, MA) or LabVIEW (National Instruments, Austin, USA) scripts. This difference in processing data has to be considered because often the results reported in literature are not obtained by a commercial-ready solution. Clinicians that cannot rely on the support of technical staff may encounter some difficulties in choosing the most accurate hardware-software setting. Others details such as position, model, sampling rate and sensitivity of IMUs are provided in Table II.

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Table II.-IMUs' specifications declared in manuscripts.

	Model	Embedded sensors	N. of IMUs	Position	Sampling rate (Hz)	Sensitivity
Buganè 2012[41]	F4A - Free4Act (LorAn Engineering, Bologna, Italy)	A3	1	L4-L5 space	50 Hz	±3 G
Godfrey 2015[119]	Axivity AX3 sensor (AX3, Axivity, York, Uk)	A3	1	L5	100 Hz	±8 G
Hartmann 2009[128]	Dynaport MiniMod (McRobert BV, The Hague, The Netherlands)	A3	1	S2	100 Hz	
Lord 2008[123]	Vitaport Activity Monitor (TEMEC Instruments Inc., Heerlen, The Netherlands)	A (not specified)	5	trunk sagittal, trunk longitudinal, trunk transverse, right leg, left leg	32 Hz	
Byun 2016[100]	FITMETER (FitLifeInc, Suwon, Korea)	A3	1	L3 -L4	32 Hz (data resampled at 100 Hz)	±8
Del Din 2016[69]	Axivity AX3 sensor (AX3, Axivity, York, Uk)	A3	1	L5	100 Hz downsampled to 50 Hz	±8
Kluge 2017[124]	Shimmer3 sensors (Shimmer, Dublin, Ireland)	A3+G3	2	attached on each shoe below the ankle joint (external)	102,4 Hz	±8, ±500°/s
Köse 2012[120]	Free Sense (Sensorize, Italy)	A3 + 2 G2	1	fixed to the subject's belt on the right side of the body at the pelvis level	100 Hz	accelerometer: 0.0096 m/s^2 angular rate resolution: 0.2441 deg/s
Trojaniello 2015[122]	Opal (APDM, Portland,USA)	A3 + G3	1	Z-method: S2 S-method: Waist M-method: L5	128 Hz	± 6g
Trojaniello 2014[112]	Opal (APDM, Portland, USA)	A3 + G3	2	subject's ankle	128 Hz	± 6g
Item-Glatthorn 2012[125]	IDEEA LifeGait (MiniSun, Fresno, California,USA)	A2	5	1 torax, 2 tights, 2 feet	32 Hz	
Esser 2012[121]	Pi-Node (Philips, Eindhoven, The Nederlands)	A3+M3+3G	1	L4	100Hz	
Godfrey 2014[129]	Axivity AX3 sensor (AX3, Axivity, York, Uk)	A3	1	L5	100 Hz	±8
Schmitz-Hübsch 2016[82]	The Opal Mobility Lab (APDM, Portland, USA)		6		128 Hz	
Moore 2017[126]	Axivity AX3 sensor (AX3, Axivity, York, Uk)	A3	1	L5	100Hz	±8
Hickey 2016[127]	Axivity AX3 sensor (AX3, Axivity, York, Uk)	A3	1	L5	100 Hz	±8

Legend: A3=triaxial accelerometer, A2=biaxial accelerometer, G3=triaxial gyroscope, G2=biaxial gyroscope,3G=3 monoaxial-gyroscopes, M3=triaxial magnetometer

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Reference Systems

The reference systems used as gold standard can be divided in two groups: stereophotogrammetric system (surrounding the walkway volume) and force platforms systems (embedded in the walkway).

Three authors utilized stereophotogrammetric system as unique reference system: Köse et al.[120] used BTS Smart-D (10 cameras), Kluge et al.[124] used Simi Reality Motion System (8 cameras) and Esser et al.[121] used Qualisys OMCS (the number of cameras and their specifications has not been provided).

Del Din et al.[69] used the Vicon 612 system (8 cameras) together with two force plates (Kistler Instruments).

Twelve authors utilized the GaitRite system (CIR Systems Inc. Franklin, NJ, USA): an electronic walkway with a continuous sensing area (spatial accuracy 1,27cm, sampling frequency beween 80 and 240Hz) that can measure different length according to the model:

-nine authors[69,112,119,122,125,126,128,129] used the ~7m long and 0,6m wide model;

-two authors[100,123] used the ~3m long and 0,6m wide model;

-one author[82] used the ~5m long and 0,6m wide model.

Three authors[69,122,129] used a camera together with the force platform system in order to have a helpful video recording for the subsequent events recognition.

In the considered articles all the tests were conducted recording simultaneously the data from tested device and the reference gold standard devices.

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Test procedures

There are many differences in the route shape and the kind of gait tasks used to test the devices. Even if a linear-straight walkway is described in 13 articles, the line length isn't the same: four authors[41,69,121,124] used a 10m long route, two authors[127,128] used a 13m long route, Moore at al.[126] used a 25m long route, Byun et al[100] used a 20m long route, a 12m long route has been used un two studies,[112,122] Schmitz-Hübsch et al.[82] used a 8,1m long route, Item-Glatthorn et al.[125] used a 7,32m long route. Lord et al.[123] doesn't provide any information about the route length (but GaitRite length was 4,5m). A 25m "0" shaped closed route (2 straight-ways and 2 curves) was used in 3 articles.[119,120,129]

Gait task requested were different and can be organized in 2 groups:
-test managed with a single lap: from the origin of the route to its end;
-test conducted during a defined time span with multiple consecutive laps or until a prefixed number of laps. More detailed informations about the test procedures can be found in Table III.

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Table III.-Test Procedures.

	Task
Buganè 2012[41]	The subjects were asked to stand up and remain in the up-right posture for a few seconds and then to walk barefoot along a 10-m pathway, at a self-selected speed. This exercise was repeated 5 times for each participant
Godfrey 2015[119]	Participants walked at their preferred speed during 2 minutes along a closed route
Hartmann 2009[128]	Subjects performed four trials each at a slow, preferred and fast speed and they always started with the preferred speed. The order of the other two walking speeds was randomized.
Lord 2008[123]	Two trials were performed for each of these conditions. In the first participants stood up, walk towards the table at the end of the walkway, picked up a tray which had two plastic beakers filled with water to a standard level placed on it, carried the tray back to the table positioned next to their chair and sat down. In the second task participants walked as for precedent condition, whilst at the same time counting tones played on a tape recorder, the count was reported to the tester. All participants were asked to walk at their preferred speed in all tasks. Authors divided the obtained data into 4 levels of task complexity for data analysis: single task (walk: W); dual motor task (walk and carry: WM); dual cognitive task (walk and talk: WC); multiple motor/cognitive task (walk, carry and talk). The data recorded during the turns were excluded from the analysis. (Only the data obtained during the single task W were considered in this review).
Byun 2016[100]	Each subject was barefoot and sat in a chair facing the walkway, then raised from the chair observing a start sign, walked straight to the end of a 20-m flat straight walkway, turn around without stopping, walk back to the chair at a preferred, comfortable walking speed, and sit again. This procedure has been repeated three times.
Del Din 2016[69]	Each subject performed a 10m walking test 4 times.
Kluge 2017[124]	Participants walked for four times a straight 10m distance with turning movements at three different self-selected walking speeds (fixed order normal, slow, fast).
Köse 2012[120]	Subjects performed 10 laps without stopping, changing speed every 2 laps (2 laps at slow speed, 2 at comfortable speed, 2 at fast speed, then 2 at comfortable speed and finally 2 at slow speed)
Trojaniello 2015[122]	Subjects were asked to walk back and forth for about 1 min at self-selected comfortable speed, wearing their own shoes.
Trojaniello 2014[112]	Subjects were asked to walk back and forth for about 1 min at self-selected comfortable speed, and at higher speed, wearing their own shoes.
Item-Glatthorn 2012[125]	The subjects completed 1 familiarization trial followed by 3 experimental trials at 2 self-selected speeds (normal then fast).
Esser 2012[121]	The subjects performed, at a self-selected walking speed, a 10m walking test (wt) (after 2minutes wt) and the recorded time was taken from a standing start to a standing finish including gait initiation and termination.
Godfrey 2014[129]	The subjects performed two walking tasks at different self-selected speeds (preferred and fast). Each walk was performed until 5 laps. Gait was sampled as participants walked over the GaitRite. The middle three walks of each task have been used for analysis.
Schmitz-Hübsch 2016[82]	Subjects walked from 1.5 m before to 1.5 m beyond the active GaitRite recording distance (5,1m) twice in each of five different subjective speeds (comfortable – slow – very slow – fast – maximal).
Moore 2017[126]	Patients walked for 2 minutes continuously around a 25 m "0" shaped track at self-selected speed.
Hickey 2016[127]	The subjects executed 8 single task along a 13m walkway, turning around and walk at their preferred walking pace.

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Only 6 authors provided information's about the use of the shoes during the tests: in two study[41,100] subjects were barefooted, and in other four studies[112,122,124,128] shoes were allowed. Kluge et al.[124] specified that all subjects wore the same shoe model.

Only 5 authors reported information's about walking aids:

-Hartmann et al.[128] not allowed the use of aids in healthy elderly subjects;

-in other two articles canes or tripods have been allowed if used in daily life.[112,122]

-Moore et al.[126] allowed them too but data for 2 participants who wore a fixed plastic ankle-foot orthosis (AFO) were removed from the analysis because of the nature of the AFO impacting on heel strike.

- Hickey et al.[127] also allowed the use of walking aids but repeated the statistical analysis removing data for 5 participants who used walking aids.

Outcomes

In order to validate the use of inertial sensors in gait analysis, the authors focused on different spatio-temporal gait parameters, as reported in Table IV.

- Step length has been considered in 11 articles, in particular 6 articles measured it in meters;[41,69,123,126–128] 4 articles measured it in centimeters .[100,119,125,129] Köse et al.[120] did not specify the measure unit.

- Step time (in seconds) has been considered in 12 articles,[41,69,100,112,119–122,126–129] Buganè et al.[41] and Köse et al.[120] divided left and right step time.

- Cadence has been assessed in 6 articles: in strides/min in 1 paper,[41] in steps/min for the other 5 authors.[82,100,123,125,128]

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- Stride length has been measured in 3 articles, Esser et al.[121] used the centimeter, Buganè et al.[41] used the meter. Schmitz-Hübsch et al.[82] used the percentage on stature.

- Stride time (in seconds) has been considered in 6 articles.[41,82,112,119,122,124,129]

-Stance time has been considered in 8 articles: in 7 of them[69,112,119,122,124,126,127] it has been measured it in seconds, Buganè et al.[41] measured it as percentage of the gait cycle.

- Swing time has been measured in 9 manuscripts: Buganè et al.[41] considered it as percentage of gait cycle, the others[69,112,119,122,124–127] measured it in seconds.

- Gait speed has been measured in 9 articles.[41,100,112,121–125,128,129] - Stride Velocity in cm/s has been measured only in one article.[82]

- Step velocity has been considered in 4 manuscripts.[69,119,126,129]

- Single support duration has been considered only in 1 article and measured it in % of gait cycle duration.[41]

- Double support duration has been considered in 3 articles, Buganè et al.[41] measured it in % of gait cycle duration, Item-Glatthorn et al.[125] and Schmitz-Hübsch et al.[82] measured it seconds.

- Total walked distance has been measured only in one article.[120]

- The duration of the Gait Cycle (in seconds) has been considered only in one article.[125]

- Heel strike detection has been considered only in one study.[120]

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Table IV.-Outcomes.

	Step lenght	Step time	Stride time	Stance time	Swing time	Gait Speed	Cadence
Buganè 2012*[41]	YES	YES	YES	YES	YES	YES	YES
Godfrey 2015*[119]	YES	YES	YES	YES	YES		
Hartmann 2009*[128]	YES	YES				YES	YES
Lord 2008*[123]	YES					YES	YES
Byun 2016*[100]	YES	YES				YES	YES
Del Din 2016*[69]	YES	YES		YES	YES		
Kluge 2017*[124]			YES	YES	YES	YES	
Köse 2012[120]	YES	YES					
Trojaniello 2015[122]		YES	YES	YES	YES	YES	
Trojaniello 2014[112]		YES	YES	YES	YES	YES	
Item-Glatthorn 2012[125]	YES				YES	YES	YES
Esser 2012[121]		YES				YES	
Godfrey 2014[129]	YES	YES	YES				
Schmitz-Hübsch 2016[82]			YES				YES
Moore 2017[126]	YES	YES		YES	YES		
Hickey 2016[127]	YES	YES		YES	YES		

Legend: *=Studies included in Meta-analysis.

Meta-analysis

In order to conduct a meta-analysis, the authors searched for the necessary data (sample size, mean and standard deviation of both IMU's and gold-standard's values) where available and aligned them to the same measurement unit where necessary. Variables not available or undefined in selected articles were not considered.

Godfrey at al.[119] reported the data distinguishing the two "Young healthy participants (YHP)" and "Older healthy participants (OHP)" subgroups: this distinction has been maintained in order to minimize the error in the manipulation of values.

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Seven different meta-analyses were therefore performed for the following gait parameters:

-Gait speed: 5 studies,[41,100,123,124,128] 149 subjects,

[PLACE HERE FIG. 2]

Figure 2. Meta-analysis and forest plot relative to the standardized mean difference of Gait speed between accelerometers and Gold Standard. Random Effects model, τ^2 estimator: Restricted Maximum Likelihood Estimator. τ^2 = 0.0, I^2= 0.0 %, H^2=1.0, Q=1.420, p =0.841.

-Step length: 6 studies[41,69,100,119,123,128], 245 subjects,

[PLACE HERE FIG. 3]

Figure 3. Meta-analysis and forest plot relative to the standardized mean difference of Step length between accelerometers and Gold Standard . Random Effects model, τ^2 estimator: Restricted Maximum Likelihood Estimator. τ^2 = 0.082, I^2= 57.9 %, H^2=2.373, Q=14.32, p=0.026.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants ".

-Step time: 5 studies[41,69,100,119,128], 234 subjects,

[PLACE HERE FIG. 4]

Figure 4. Meta-analysis and forest plot relative to the standardized mean difference of Step time between accelerometers and Gold Standard. Random Effects model, τ^2 estimator : Restricted Maximum Likelihood Estimator. τ^2 = 0.0169, I^2= 24.7 %, H^2=1.328, Q=5.723, p = 0.334.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants ".

-Stance time: 3[69,119,124] studies, 140 subjects

[PLACE HERE FIG. 5]

Figure 5. Meta-analysis and forest plot relative to the standardized mean difference of Stance time between accelerometers and Gold Standard . Random Effects model, τ^2

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estimator : Restricted Maximum Likelihood Estimator. τ^2 = 1.39, I^2= 94.4 %, H^2=17.7, Q=49.6, p < 0.001.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants ".

-Stride time: 3 studies[41,119,124], 110 subjects,

[PLACE HERE FIG. 6]

Figure 6. Meta-analysis and forest plot relative to the standardized mean difference of Stride time between accelerometers and Gold Standard. Random Effects model, τ^2 estimator: Restricted Maximum Likelihood Estimator. τ^2 = 0.0, I^2= 0.0 %, H^2=1.0, Q=1.804, p = 0.614.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants ".

-Cadence: 4 studies[41,100,123,128], 138 subjects,

[PLACE HERE FIG. 7]

Figure 7. Meta-analysis and forest plot relative to the standardized mean difference of Cadence between accelerometers and Gold Standard. Random Effects model, τ^2 estimator : Restricted Maximum Likelihood Estimator. τ^2 = 0.693, I^2= 89.7 %, H^2=9.76, Q=14.9, p = 0.002.

-Swing time: 3 studies[69,119,124], 140 subjects,

[PLACE HERE FIG. 8]

Figure 8. Meta-analysis and forest plot relative to the standardized mean difference of Swing time between accelerometers and Gold Standard. Random Effects model, $\tau 2$ estimator : Restricted Maximum Likelihood Estimator. τ^2 = 0.393, I^2= 83.3 %, H^2=5.98, Q=19.8, p < 0.001.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants".

Information from the forest plots

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Each forest plot reports a synthesis of the standardized mean differences (SMD) of the data obtained from inertial sensors and those obtained from Gold standard. SMD is the difference in the mean value of the two groups divided by the standard deviation. It represents a measure of the so called "effect size".

In the present case, a positive SMD indicates a greater mean value measured by the IMUs as compared to Gold standard, while a negative value indicates a greater mean value for the Gold standard.

Each square in the plot represents the SMD value obtained from the study labeled on the left of the chart. The error bars correspond to the 95% confidence interval (95% CI) for the SMD (rightmost values on the plot). The higher the 95% CI, the higher the uncertainty about the SMD. The width of each square is related to the sample size of the study and to the weight that the study will have in the final synthesis (in percent, first values on the right of the plot). Greater squares represent larger studies and will have higher importance in the analysis.

The diamond on the bottom of the plot represents the final synthesis for all the studies, with the 95% CI, reported in brackets. If the 95% CI includes zero, no statistically significant difference may be claimed about IMUs and Gold standard measurements. On the contrary, if the 95% CI does not include zero, a statistically significant difference suggesting a different behavior among the instruments exists.

An important information about the analysis regards the heterogeneity of the studies included in the synthesis, indicated by the coefficient I^2**.** I^2 values greater than 75% indicate large heterogeneity, meaning relevant discrepancies among the studies, as in the case of opposite results. Extra care should be taken when drawing any conclusion from studies with high heterogeneity: even if no statistically significant difference seems to be

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found between IMUs and Gold standard measurements for swing time and cadence, the I^2 values are respectively 83.3% and 89.7%.

Among our data only the meta-analysis relative to stance time seems to indicate some significant difference between the two instruments, with IMUs overestimating the measure with respect to Gold standard.

The systematic study of human motion, traditionally performed in a motion Lab, makes use of expensive bulky equipment (e.g. optoelectronic, instrumented walkway). These techniques are considered the gold standard in the field of gait analysis. Recently a growing interest arose towards the use of IMUs in clinical practice as they offer a cheap and portable alternative to the traditional equipment. The low power consumption of these devices allows to implement lightweight wireless devices that minimally impact the comfort of the patient during examination. However, the increasing popularity of these devices is not supported by either precise information on their reliability or guidelines for their use in ambulatory setting. This review gathers studies examining inertial sensors for gait analysis in both healthy and pathological adults and comparing them to traditional systems. Furthermore, in an attempt to define directions for clinicians, we selected studies were IMUs were suitably designed for clinical application, easy to propose again especially in ambulatory setting and with regarding on a gait analysis as much as possible detailed. Although now IMUs are available in common devices like smartphones and although they often have excellent hardware (e.g. sensor), they are often not accompanied by software suitable for clinical use. Furthermore, they do not have standard shapes and sizes, and therefore it is difficult to find fixing and measuring methods that guarantee

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repeatable and cross-platform results. For that reasons we excluded smartphones, step counters, pedometers, wrist activity trackers or similar devices used as inertial sensors, or walking test conducted on treadmill.

Unfortunately, no Randomized Controlled Trials (RCTs) have been found after the application of our search strategies and performing a meta-analysis with the included studies was not simple because of the heterogeneity of the presented outcomes. So we decided to combine only studies were similar outcomes were discussed, because subgroup analysis is the most clinically helpful, as it can point to specific patient or intervention characteristics in which the intervention has an effect and can be directly translated to clinical practice.[130] With our studies, we can perform a subgroup analysis only for healthy subject because few studies consider the same pathologies. Even if 6 manuscripts[69,112,121–124] tested the devices with patients affected by Parkinson's disease, they have not considered the same outcomes or they have not provided useful data for meta-analysis.

Despite the diversity of the tasks the subjects were assigned, among all gait parameters reported in our studies, a meta-analysis was performed for gait speed, step length, step time, stance time, stride time, cadence and swing time, and is reported in Table IV.

It is known that the reduction of gait speed and step lengths, the alteration of stance time and cadence are related to reduction of activity level and participation, that is a crucial issue in rehabilitation as described in the ICF.[5] This parameters are predictors of disability for both healthy and pathological subjects.[6,48,131–136] The objective and repeatable measure of these fundamental spatio-temporal gait parameters in a short time and with reduced costs it is a valid help for the clinicians. However with our results we cannot recommend the IMUs as the unique device for gait analysis, because it’s known

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that a complete gait assessment could be important for clinical decision. In particular three-dimensional gait analysis can help clinicians to identify the locomotor strategy used by the patients, to design a personalized locomotor training and can determine whether a patient is responding to the chosen intervention. This kind of analysis represent a more complete evaluation than the spatio-temporal parameters used alone. Currently the gait analysis, that the experts can recommend, is performed in a Motion Lab, despite its aforementioned difficulties for application in common clinical settings.[7,137]

Therefore for practical, time and economic issues the subjective evaluation of the expert clinician prevails in the common clinical practice albeit burdened by poor repeatability related to the tools used and to the observer's inexperience.[105,138–140]

Conclusions

Our results show a good agreement between IMUs and classical gait analysis for several gait parameters, supporting IMUs as a solution for capturing kinematic information over an extended space and time and even outside a laboratory in real-life conditions. Although in this review it has not been possible to analyze other gait parameters due to lack of data available in the selected literature, we believe that these parameters can allow a practical gait analysis.

This study has some potential limitations.

First we pooled data from several studies with different devices, different algorithms and different test procedures. Moreover, a larger sample of patients is needed to verify the results of present manuscript. Second, with our results, we cannot perform an accurate analysis in patients because of a lack of suitable data as the selected studies evaluate

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different pathologies or the same pathology but focusing on different outcomes. As discussed in the previous section, no RCTs have been found after the application of our search strategies, and could not be added to this review. The lack of homogeneity of the outcomes and especially of the considering tasks and some technical issues give rise to large limitations in understanding the real effectiveness of the inertial systems used on healthy or unhealthy subjects.

From a clinical perspective, the need for a global versus a partial analysis can differ according to each single case. Even today the diagnosis of gait alteration remains a specific need in rehabilitation and still remains clinical in most cases. IMUs could be an interesting solution in this specific field. Nevertheless, no standard protocols have been developed so far, making their clinical application hard at present time. Future research is needed with the aim of defining a precise protocol in terms of movements and tasks to be evaluated.

With this in mind we can support the use of IMUs for a functional gait analysis in clinical setting with good reliability. It will then be the experience of the clinician to direct the decision-making process.

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estimator : Restricted Maximum Likelihood Estimator. τ^2 = 0.693, I^2= 89.7 %, H^2=9.76, Q=14.9, p = 0.002.

Figure 8. Meta-analysis and forest plot relative to the standardized mean difference of Swing time between accelerometers and Gold Standard. Random Effects model, τ2 estimator : Restricted Maximum Likelihood Estimator. τ^2 = 0.393, I^2= 83.3 %, H^2=5.98, Q=19.8, p < 0.001.
Legend: *(YHP)* = "Young healthy participants"; *(OHP)* = "Older healthy participants".

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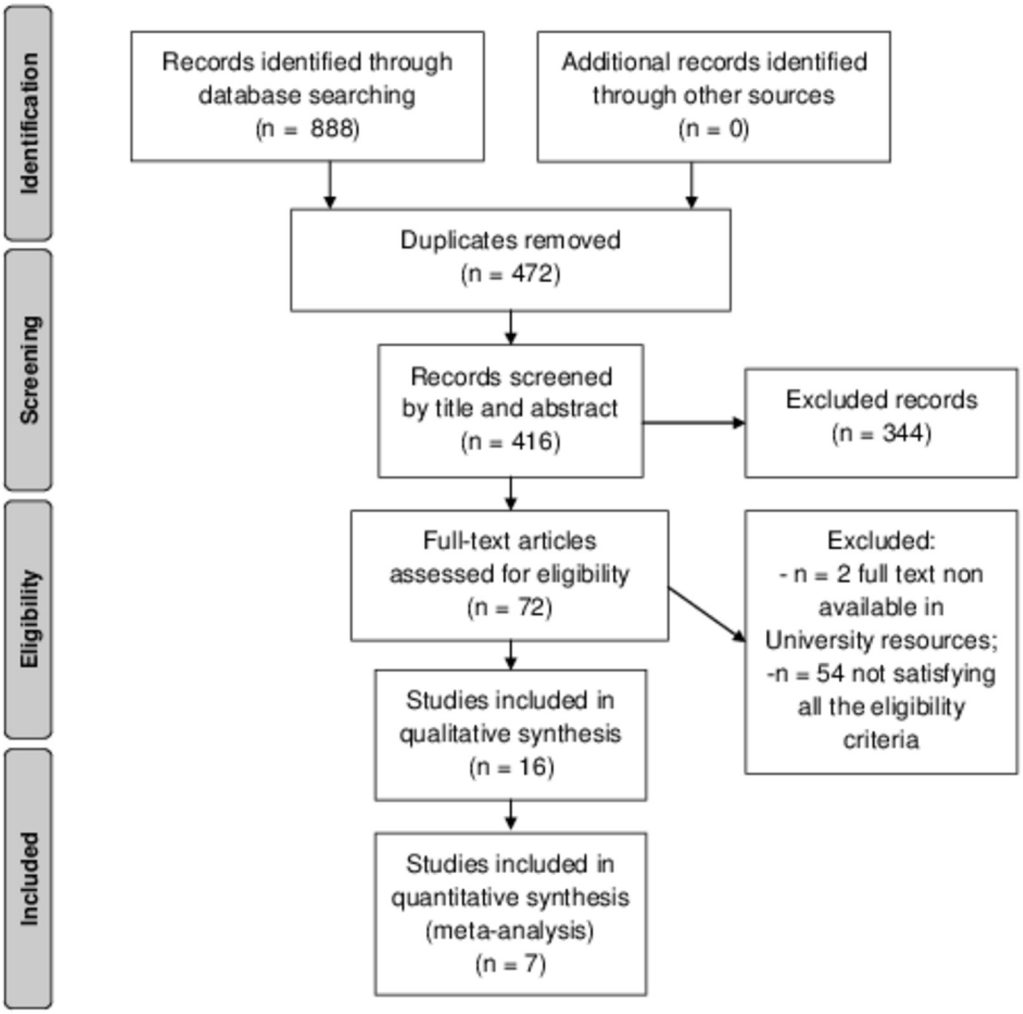

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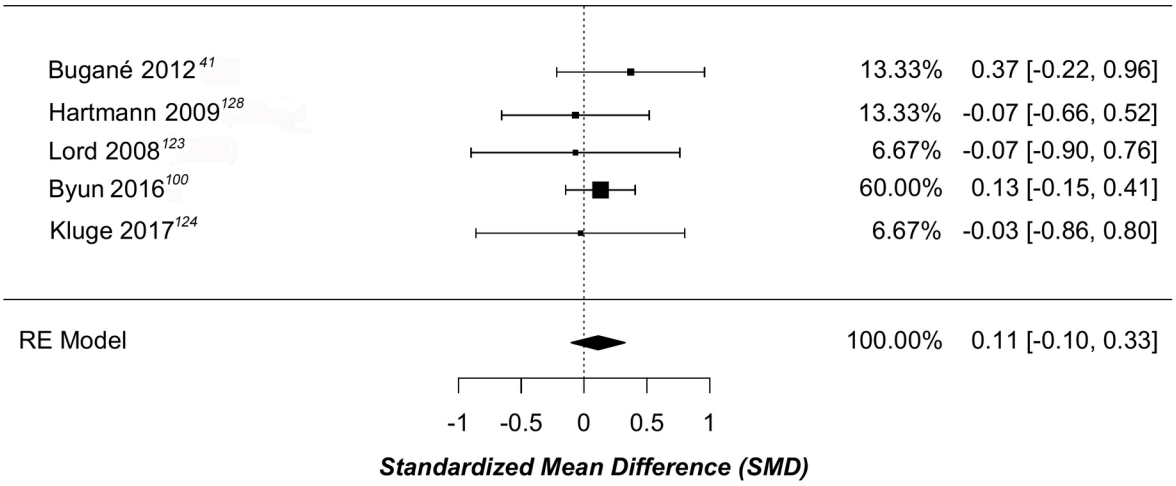

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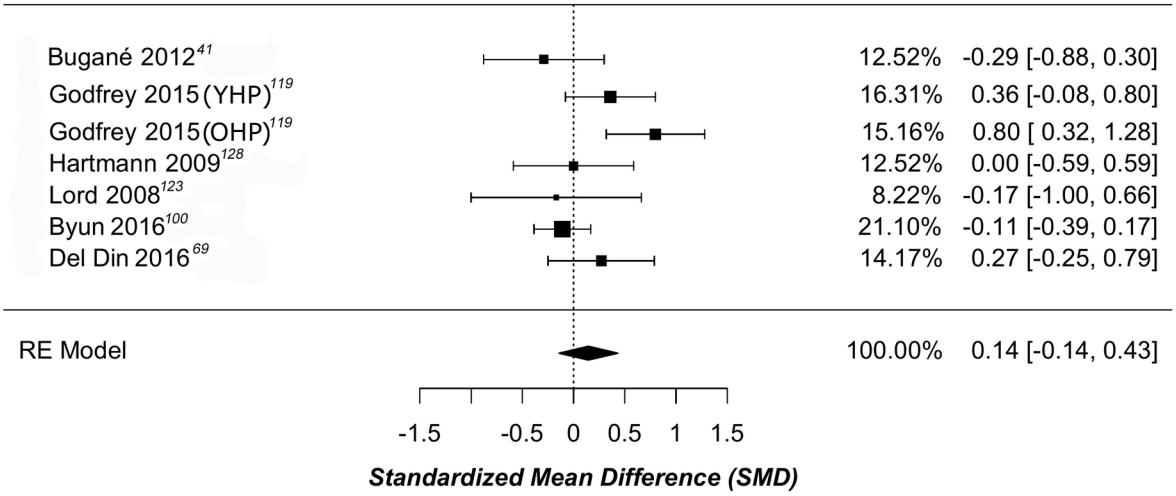

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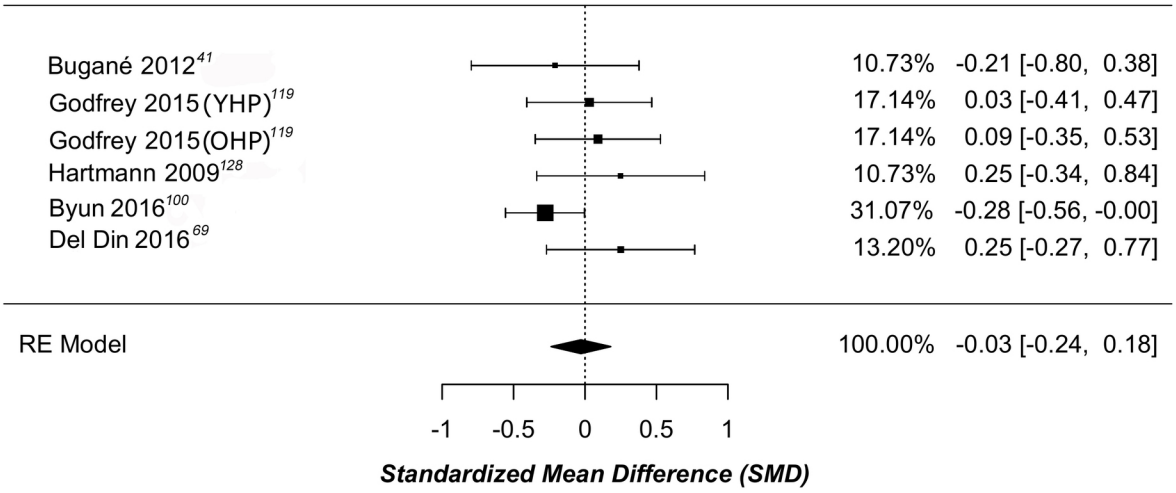

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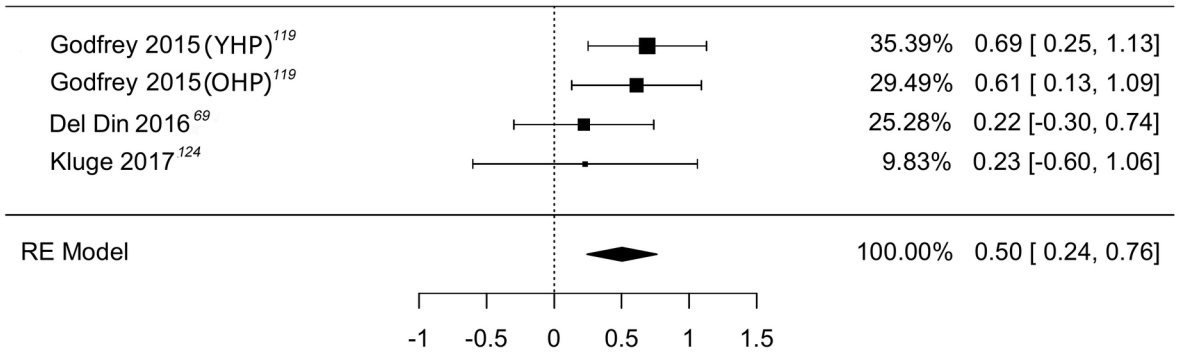

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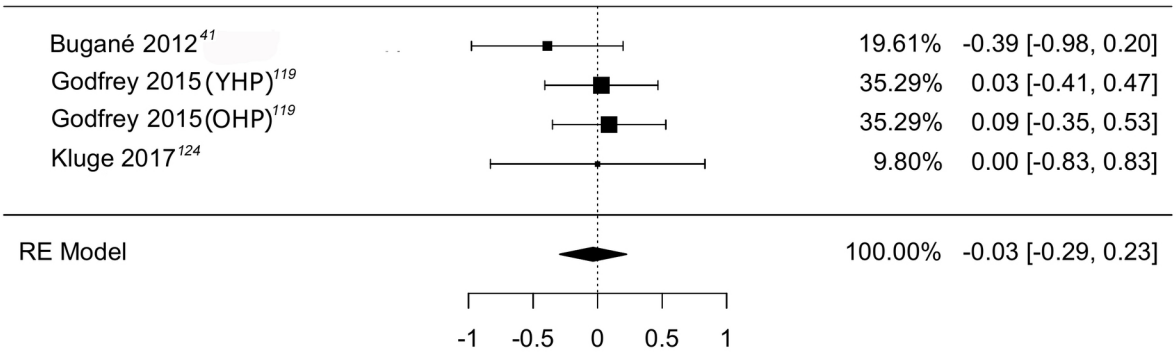

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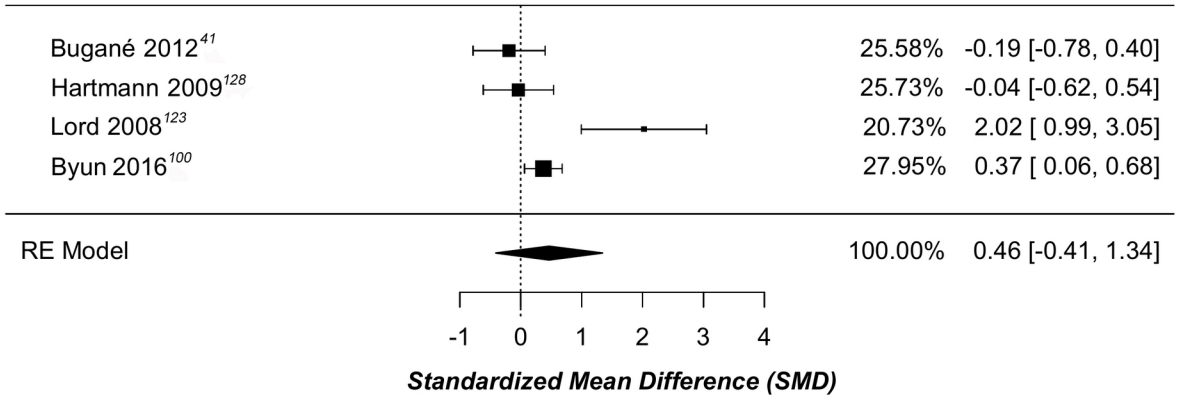

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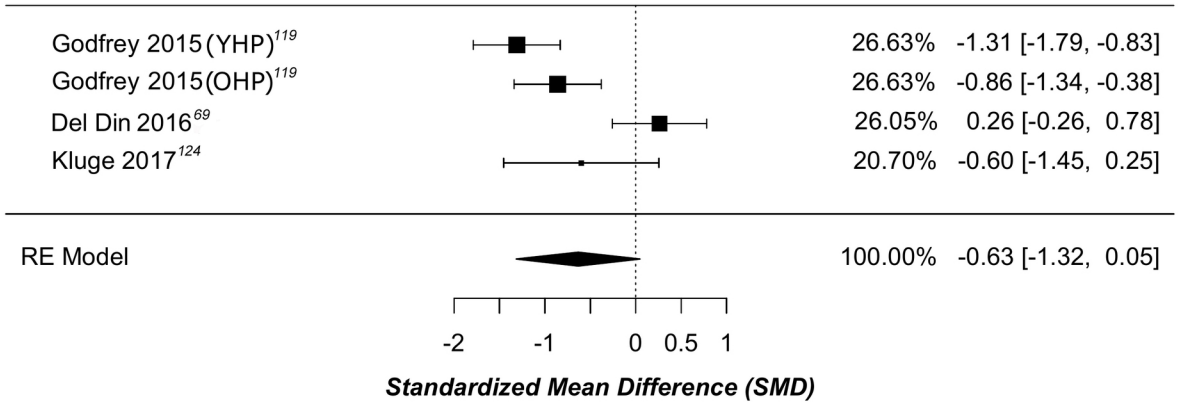

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