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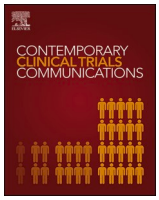

The 24-Hour Movement Paradigm: An integrated approach to the measurement and promotion of daily activity in cancer clinical trials

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ABSTRACT

Increased physical activity (PA), improved sleep, and decreased sedentary behavior (SB) are essential components of supportive care for cancer survivors. However, researchers and health care professionals have achieved limited success in improving these behaviors among cancer survivors. One potential reasoning is that, over the past two decades, guidelines for promoting and measuring PA, sleep, and SB have been largely siloed. With greater understanding of these three behaviors, health behavior researchers have recently developed a new paradigm: the 24-Hour movement approach. This approach considers PA, SB, and sleep as movement behaviors along a continuum that represent low through vigorous intensity activity. Together these three behaviors form the sum of an individual's movement across a 24-hour day. While this paradigm has been studied in the general population, its usage is still limited in cancer populations. Here, we seek to highlight (a) the potential benefits of this new paradigm for clinical trial design in oncology; (b) how this approach can allow for greater integration of wearable technology as a means of assessing and monitoring patient health outside the clinical setting, improving patient autonomy through self-monitoring of movement behavior. Ultimately, implementation of the 24-Hour movement paradigm will allow health behavior research in oncology to better promote and assess critical health behaviors to support the long-term well-being for cancer patients and survivors.

1. Increased physical activity (PA), improved sleep, and decreased sedentary behavior (SB): essential ingredients for improved health and well-being for cancer survivors

Cancer care is complex and is often associated with side effects that can impact a patient's physical health and overall well-being. Patients undergo dynamic changes in their daily activity and sleep behaviors due to the symptoms and treatment-related side effects experienced throughout their treatment and beyond [1]. The independent health effects of PA, sleep, or sedentary behavior have been examined extensively in cancer patients[2–7]. Although increasing PA, reducing SB, and improving sleep are important for the health of cancer survivors, most cancer survivors are physically inactive [8–16], spend up to 70% of their time on sedentary activities [17], and commonly present with sleep disruptions [3]. Greater understanding is therefore required of PA, SB, and sleep behaviors, how they interact, and their combined impact on cancer outcomes.

In cancer survivorship research, PA, SB, and sleep are often examined separately, either in distinct clinical trials (e.g. Refs. [18–22]) or as unique outcome measures (e.g. Refs. [23–25]). This contrasts with recent developments in the field of health behavior change. More recent approaches reflected in new Canadian and Australian national

Abbreviations: PA, physical activity; SB, Sedentary behavior; MVPA, moderate to vigorous physical activity; LPA, light physical activity; QoL, quality of life; BCS, breast cancer survivors; BMI, body mass index.

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guidelines [26–29] and by the WHO [30] have changed direction from examining PA, SB, and sleep separately to a focus on all three behaviors as markers along one movement continuum. PA, SB, and sleep are seen as interactive dimensions of movement, ebbing, and flowing over the course of the 24-hour day to create an outcome of an individual's daily movement activity (See example national movement guidelines in Table 1) [26,31,32].

This 24-Hour movement paradigm suggests that during a 24-hour day, movement can be classified on a continuum from low to high intensity [e.g., sleep, sedentary behavior (screen time, reclining, or lying down), and light, moderate, or vigorous PA]. People engage in various combinations of these movement behaviors every day [31,33]. A change in the amount of time spent in one movement behavior influences time spent in another movement behavior [26]. Thus, all three movement behaviors are inter-related and co-dependent [26]. Additionally, time spent in each movement behavior has independent and combined effects on health outcomes [31,34,35]. The message of these guidelines is clear: it is not just the 30 minutes three times a week on the treadmill or strength training that counts. All movement and, most notably, the composition of movement throughout the day matters [31,36,37].

To our knowledge, only a limited number of studies have examined the interaction of 24-hour movement behaviors in cancer survivors [22,38–42]. For instance, Vallance et al. [38] found that reallocating sleep, sedentary time, or light physical activity (LPA) to moderate to vigorous physical activity (MVPA) in a group of non-Hodgkin lymphoma survivors was associated with less fatigue but not better quality of life. Similarly, Van Roekel and colleagues [39] concluded that in colon cancer survivors, substituting 1 hour a day of sedentary time with equal time in standing or PA was associated with significantly improved disability and fatigue and better physical functioning. Studies among breast cancer survivors (BCS) have shown that replacing 30 minutes of sleep, prolonged sedentary time, or LPA with MVPA was associated with lower waist circumference and body mass index (BMI) [40] and that replacing sedentary behavior with MVPA improved cognitive function. Among renal cancer survivors, reallocating sedentary time to MVPA, LPA, or sleep at higher doses was associated with better fatigue and physical aspects of quality of life [42]. Although the results of these studies are promising, investigating the applicability and effect on health indicators of this interactive approach in the cancer population in large-scale studies is crucial. These studies could not only corroborate the value of the 24-Hour movement approach in the cancer population but also aid in the expansion of cancer survivorship exercise guidelines to cancer survivorship 24-Hour movement guidelines.

2. How can this paradigm inform the development of clinical trial interventions to promote sustained behavior change among cancer survivors?

The 24-Hour paradigm may be particularly beneficial for promoting long-term adherence to positive movement behaviors in cancer survivors. Studies examining PA programs among the cancer population show that participants find these programs helpful [43,44]. They provide physical (e.g., improved fitness, energy levels, ability to handle treatments, weight management), social (e.g., making connections and communication with other cancer survivors who understood survivorship experiences), and psychological benefits [43,44]; all of which can contribute to improving adherence [45,46].Given the physical and psychosocial barriers specific to cancer survivors and the need to find ways to promote and achieve sustained healthy behavior in this population [47], this new approach –focusing on the combination of the three movement behaviors - could aid in achieving more sustained behavior change. The paradigm could provide an opportunity for more accessible and individualized approaches to movement recommendations for cancer survivors, allowing clinical trialists and exercise physiologists to deliver movement interventions and adapt recommendations based on any physical or psychosocial barriers participants may be experiencing, such as treatment-related effects like fatigue or pain, or changes in self-efficacy or body image [43–45,48–50]. Specifically, integrating the three behaviors as a movement continuum, PA promotion for cancer survivors can take an ability-focused approach with individuals focusing on a movement behavior that meets them where they are physically and psychologically [45,50]. Patients should not have to experience negative feelings of guilt about not being able to complete 30 minutes of moderate-to-vigorous activity five days a week due to deconditioning or cancer treatment effects. Instead, cancer survivors can participate in leisurely walks, stand more, reduce recreational screen time and sedentary behavior, or develop consistent bed and wake times, with small changes being implemented over time as health and fitness improve.

3. How can this paradigm improve assessment of health behaviors in clinical trials?

Implementation of the 24-Hour movement approach can also lead to new and innovative ways of measuring and analyzing movement behaviors in clinical trials. Novel technologies, such as wearable technology and other digital health technologies, can be used to monitor activity across the 24 hour continuum outside the clinic setting and

Table 1
Canadian 24-Hour movement guidelines in children and adults.

Age	Move/PA	Sleep	Sedentary behavior
Children and youth [27] **(5–17 years)**	• ≥ 60 min of aerobic moderate to vigorous PA (MVPA) a day • ≥ 3 days of muscle and bone strengthening activities per week • Several hours of a variety of structured and unstructured light PA (LPA)	• 5–13 years: 9–11 uninterrupted hours of sleep per night • 14–17 years: 8–10 h of sleep per night • Consistent bedtimes and wake-up times	• No more than 2 h of recreational screen time per day • Limited sitting for extended periods. • Preserving sufficient sleep, trading indoor for outdoor time, and replacing sedentary behaviors and LPA with additional moderate to vigorous PA can provide greater health benefits.
Adults [26] **(18–64 years)**	• ≥ 150 min of aerobic MVPA a week • ≥ 2 days of muscle strengthening activities using major muscle groups per week • Several hours of LPA, including standing	• 7–9 h of good quality sleep per night on a regular basis • Consistent bedtimes and wake-up times	• Limiting sedentary time to ≤8 h which includes o ≤ 3 of recreational screen time o Breaking up long periods of sitting as often as possible • Replacing sedentary behavior with additional PA, and trading LPA for more MVPA, while preserving sufficient sleep, can provide greater health benefits
65 & older [26]	• ≥ 150 min of aerobic MVPA a week • ≥ 2 days of muscle strengthening activities using major muscle groups per week • PA that challenge balance • Several hours of LPA, including standing	• 7–8 h of good quality sleep per night on a regular basis • Consistent bedtimes and wake-up times	• Limiting sedentary time to ≤8 h which includes o ≤ 3 h of recreational screen time o Breaking up long periods of sitting as often as possible Replacing sedentary behavior with additional PA, and trading LPA for more MVPA, while preserving sufficient sleep, can provide greater health benefits

allow for patients to engage in their own care and monitor their own activity [51–54]. Real-time monitoring of the three movement behaviors may also lead to the earlier detection of functional decline, disease progression, or other clinically important outcomes [52,55].

However, considerations should be taken into account when collecting, analyzing, and reporting these health behaviors, which are often related and highly correlated [56]. While interpretation of the behaviors may be integrated, PA, SB, and sleep, should be assessed and collected separately using validated assessment methods such as accelerometry or activity tracking with commercially-available devices (e.g., Fitbit, Garmin, Apple Watch), activity logs, ecologic momentary assessment, or patient-reported surveys. If using accelerometers or wearable devices to capture movements behaviors, patients are required to wear the devices for a 24-hour period including during nighttime sleep. It is important to define the minimum wear-time of the devices a priori and align the duration of wear-time with the study timeline and other data collection timepoints. If using patient-reported activity, it is important to use validated surveys for the population of interest and supplement with other assessments to reduce the potential reporting bias and under or [56] over-estimation of activity associated with self-reported PA [51,57,58].

When analyzing the different movement behaviors, statisticians should define how the data will be summarized (e.g., means, median), specific metrics (e.g., change from baseline), and the specific time interval(s) (e.g., days, weeks, months). These health behaviors (PA, SB, sleep) should first be treated as continuous variables using standardized metrics, and further categorized into PA categories (moderate-to-vigorous-intensity and light intensity), SB time, and sleep duration. Methods to handle missing data should be included in the statistical analysis plan and imputation methods should be applied when analyzing these data [56,59–61]. Methods that integrate or combine the different movement behaviors as a summary or index are encouraged to be used. For instance, 24-hour movement behaviors can be analyzed using compositional analysis [62] to better understand movement behavior as a whole and not as independent activities. In this case, multivariable Generalized Dirichlet Multinomial models [38] would be fit to analyze compositional data (24-hour movement continuum) as the response variable with patient or clinical characteristics as covariates. Expected changes on selected endpoints could be presented with compositional isotemporal substitution plots [41,42]. Other indexes such as the activity fragmentation index [63], may also be computed and used as the response variable when performing analyses. Results, including visual representations and graphical displays, should account for the integrated movement behaviors and be presented in a way that can be easily interpreted and understood by readers and the public.

4. Conclusion: use of the 24-Hour movement continuum to support the goals of sustained movement and positive health outcomes in cancer survivors

24-Hour movement can serve as an important intervention framework and assessment tool in clinical trials. The 24-Hour movement paradigm allows for a more comprehensive, holistic, and biopsychosocial approach towards PA that will improve our understanding of a patient's movement behaviors and consequently inform the development of tailored interventions and improve patient outcomes [33,64]. The integration of these movements can further illuminate the important and nuanced effects that an intervention or treatment may have on a patient's overall health and well-being. As the broader field of health promotion and behavior change implements this new concept, we recommend cancer researchers consider adopting the 24-Hour movement paradigm as a framework when designing clinical trials, as well as when measuring and interpreting movement behaviors.

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Author contributions

Celina Shirazipour: Conceptualization, Writing – original draft, Writing - review & editing, Supervision. **Carolina Raines:** Writing – review & editing. **Marcio Diniz:** Writing – review & editing. **Sarah-Jeanne Salvy:** Writing – review & editing. **Robert Haile:** Writing – review & editing. **Stephen J. Freedland:** Writing – review & editing. **Arash Asher:** Writing – review & editing. **Jennifer R. Tomasone:** Conceptualization, Writing – review & editing. **Gillian Gresham:** Conceptualization, writing- Review & editing, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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