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Examining building blocks of well-being beyond PERMA and self-report bias

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ABSTRACT

Recent debates in the *Journal of Positive Psychology* about the nature and usefulness of PERMA have created confusion about its contribution toward the understanding and prediction of well-being. This empirical study was designed to clarify several issues that have emerged in these recent articles. Using a multi-trait multi-method (MTMM) research design with 220 knowledgeable co-worker pairs ($N = 440$), it was found that the 5 PERMA building blocks of well-being (positive emotions, engagement, relationships, meaning, and accomplishment) and 4 additional potential building blocks of well-being (physical health, mindset, environment, and economic security) significantly predicted SWB above and beyond self-report and mono-method bias. This is one of the first empirical studies to test the PERMA building blocks of well-being beyond the sole use of self-reports, and illustrates that the building blocks can be strong predictors of well-being in some populations.

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Seligman (2011) proposed five building blocks of well-being, which he called PERMA:

Positive emotions	– experiencing happiness, joy, gratitude, etc.
Engagement	– using your strengths to meet challenges; experiencing flow
Relationships	– connecting with others; love and be loved
Meaning	– connect to meaning; find your purpose
Accomplishment	– pursue and accomplish goals; strive for greatness

More recently, Seligman (2018) hypothesized these building blocks were neither orthogonal nor exhaustive and encouraged researchers to explore additional building blocks of well-being beyond PERMA. Much empirical research to date has been conducted on the PERMA building blocks (see Donaldson, 2019; Donaldson et al., 2019; Heshmati et al., 2020; Kern, Waters, Adler, & White, 2015a; Watanabe et al., 2018) often using the PERMA-Profilier (Butler & Kern, 2016).

After extensive grounded applied research in the workplace, carefully reviewing the empirical studies using the PERMA-Profilier, in combination with conducting systematic reviews and meta-analyses on positive psychology interventions at work, four additional building blocks of well-being were identified as worthy of future exploration (Donaldson, 2019; Donaldson et al., 2019; 2019b; Neumeier et al., 2017; Watanabe et al., 2018). The measurement of these four proposed building blocks were validated by Donaldson (2019) and Donaldson and Donaldson (under review) and include:

We will refer to the nine building blocks above as Positive Functioning at Work. Please note Positive

Functioning at Work is equivalent to the five PERMA

Physical Health	– biological, functional, and psychological health assets
Mindset	– future-oriented, growth mindset, perseverance
Environment	– spatiotemporal elements, such as access to natural light, nature, physiological safety
Economic Security	– perception of financial security

Building Blocks plus the 4 additional proposed building blocks (PERMA+4).

Measurement concerns with PERMA

Goodman et al. (2018) found that the PERMA building blocks are strongly associated with subjective well-being (SWB), and may even be synonymous. Goodman et al. (2018) and Kashdan (2017) concluded that PERMA:

- is not a new type of SWB,
- does not yield any insights beyond SWB, and
- that PERMA is redundant with SWB.

Seligman (2018), on the other hand, argued these data strongly support his theory of PERMA by demonstrating that PERMA not only successfully captures well-being, but identifies (at least some of) the building blocks that constitute well-being. Seligman (2018) pointed out that Goodman and Kashdan's assertion 'he claimed PERMA constituted a different kind of well-being,' rather than its building blocks, was at best a misunderstanding.

Kashdan (2017) argued that PERMA is not useful because:

- (a) it emerged from a 'trade' book;
- (b) it is prematurely used too widely by clinicians, businesses, and others;
- (c) the elements are arbitrary;
- (d) there is no way to choose between PERMA and other theories that postulate 196 or more alleged elements.

In response, Seligman (2018) strongly disagreed with Kashdan's arguments and suggested several criteria that might be used to evaluate a theory of the building blocks of well-being:

- (1) The elements contribute to well-being (The.98 correlation with SWB strongly

confirms that for PERMA in Goodman et al., 2018)

(2) Many people pursue each element for its own sake and not just to serve another element (PERMA modestly satisfies this, see pp. 16–20 of Seligman (2011)).

(3) The list of elements is exclusive and exhaustive (PERMA may be exclusive, but it is certainly not exhaustive. e.g., physical health, vitality, and responsibility are additional candidate elements)

(4) The elements lead to specific interventions to build each element and SWB (PERMA meets this modestly).

(5) The list is parsimonious (five does rather better than 196).

(6) Each element can be defined and measured independently

of the other elements.

We applaud those on both sides of the argument about the value of PERMA, and appreciate how this rather lively exchange has shed more light on the proposed relationships between the PERMA building blocks and SWB.

Self-report bias

While the above debate helped clarify the conceptual disagreements about PERMA, the data presented by Goodman et al. (2018) were based solely on self-reports collected from participants on Mturk at one point in time. One highly likely rival explanation for Goodman's strong cross-correlations is that they are an artifact of self-report and/or mono-method bias (see Donaldson & Grant-Vallone, 2002; Seligman, 2018). Unfortunately, this problem is rampant in well-being and positive psychology research. For example, in a recent review of more than 970 peer-reviewed positive psychology articles, Ackerman et al. (2018)

found that 78% of the empirical research on positive psychology topics used self-reports and 68% used only self-reports. It is well-known that the sole use of one type of measure like self-report can strongly inflate correlations like those produced in the Goodman et al. (2018) Mturk study.

The current study

This study was designed to examine the relationships between possible building blocks of well-being and SWB above and beyond self-report bias. This is one of the first empirical studies to date to test the PERMA building blocks beyond solely using self-reports. The design we describe below uses both self and knowledgeable collateral reports to test the following hypotheses:

- (1) Self-reported PERMA will significantly predict self-reported and collateral-reported Subjective Well-Being.
- (2) Self-reported Positive Functioning at Work will significantly predict self-reported and collateral-reported Subjective Well-Being.
- (3) Collateral-reported PERMA will significantly predict self-reported and collateral-reported Subjective Well-Being.
- (4) Collateral-reported Positive Functioning at Work will significantly predict self-reported and collateral-reported Subjective Well-Being.

Method

Participants

A total of 440 participants in 220 knowledgeable co-worker pairs participated in the study. The average age of the employees was 40 years old ($SD = 12$) with 56% female ($n = 247$) and 43% male ($n = 191$). Two participants reported their sex as 'other.' The majority of participants were White (73.8%, $n = 296$), African American (13.7%, $n = 55$), and Asian (12.4%, $n = 50$). Most respondents reported having a Bachelor's degree (38.3%, $n = 167$), followed by Masters degree (26.2%, $n = 114$), Associate degree (19.7%, $n = 86$), High School or less (8.0%, $n = 36$), and Doctorate degree (7.0%, $n = 32$). Five people did not report their educational attainment. Of participants who reported their work industry, Other (41.6%, $n = 84$), banking (29.2%, $n = 59$), and healthcare (29.2%, $n = 59$) were the most represented. Other industries included education, government, manufacturing, and non-profit, among others. Most respondents reported

that their income was between 25–49 k (24.2%, $n = 106$), 50–75 k (26.5%, $n = 116$), or 75–99 k (21.0%, $n = 92$).

Procedure

A Qualtrics panel to source knowledgeable employee-coworker pairs from full-time employees in a sample of U.S. corporations was used to collect the data for this multi-trait mult-method study (see Donaldson & Grant-Vallone, 2002). Qualtrics uses Grand Mean certified sample partners to ensure reliability and validity, checks every IP address, and implements a sophisticated digital fingerprinting technology. Qualtrics panel partners used stratified random sampling to approximate employees in the general population, and then randomly assigned the survey to eligible participants. Respondents were sent an email invite, including information on the research purposes and length of the survey. Qualtrics uses an incentive system (e.g., gift cards, airline miles, cash) to encourage participation.

The survey was divided into two sections. In the first part, employees completed the 29-item Positive Functioning at Work (PF-W) scale and a five item Satisfaction with Life Scale, also known as SWB (Diener et al., 1985). The second part of the study included a transition between the employee and their closest coworker. The instructions read, 'For the next stage of the survey, we ask that you please answer the questions about your closest coworker. Thank you for your participation.' The coworker then completed the same items about their colleague. Our final items assessed demographic characteristics, such as gender, ethnicity, education, and income.

The research protocol was approved by Claremont Graduate University's IRB. Please see Appendix A for the final instrument.

Measures

PERMA and Positive Functioning at Work (PF-W)

The 29-item PF-W scale was developed and validated by Donaldson (2019) and Donaldson and Donaldson (under review). This measure assessed the 5 PERMA building blocks of well-being plus the additional four building blocks of physical health, mindset, environment, and economic security in the workplace context. Confirmatory factor analytic models have supported a general factor structure of PF-W with nine lower order dimensions, and exhibited validity with other well-being and performance measures (see Donaldson, 2019). Respondents reported their level of positive functioning

on PF-W using a 7-point Likert-type scale from 1 (*Strongly Disagree*) to 7 (*Strongly Agree*).

Satisfaction with life scale

The Satisfaction with Life Scale (SWLS) is one of the most widely implemented subjective well-being scales in the positive psychology literature (Diener et al., 1985). With close to 23,000 citations on Google Scholar, SWLS has been validated not only at the population level in the U.S. but also in international populations (Ackerman et al., 2018). This was the same SWB scale used in the Goodman et al. (2018) Mturk study. One major strength of SWLS is that it consists of only five Likert-type items.

Analytic strategy

All analyses were conducted in R (version 3.6.1, R Foundation for Statistical Computing, 2019) using the psych (Revelle, 2019), Hmisc (Harrell, 2019), and QuantPsyc (Fletcher, 2010) packages. Pearson's linear correlations were used to assess convergence between study variables. and Regression strategy. Our final analyses fit general linear regression models to predict self- and collateral-reported SWB. Working likelihood ratio (Rao-Scott) tests were used to reveal significant study predictors (Rao & Scott, 1984).

Results

A total of 212 pairs were included in the final analysis after removing incomplete responses, long string invariant responses, and multivariate outliers using Mahalanobis distance values. No univariate outliers were detected. Descriptive statistics confirmed that data were normally distributed (skewness $\pm 3 \geq$ and kurtosis $\pm 10 \geq$; Kline, 2010). Convergence tests between self-reported and collateral-reported PERMA and Positive Functioning at Work (PF-W; PERMA+4) and SWB demonstrated that the correlation between self-reports and collateral-reports for each element of PFW and SWB were significant and strong, ranging from $r = .58$ to $.87$. Tables 1 and 2 present descriptive statistics and correlations between self-reports and collateral reports for PFW and SWB.

Hypothesis 1 stated that self-reported PERMA will significantly predict self-reported and collateral-reported Subjective Well-Being (SWB). As shown in Table 3, self-reported PERMA was a significant predictor for both self-reported SWB and collateral reported SWB ($\beta = .84$, $p < .001$; $\beta = .70$, $p < .001$, respectively). These findings provide support for *Hypothesis 1*.

Next, we tested *Hypothesis 2* that self-reported PFW will significantly predict self-reported and collateral-

Table 1. Means, SDs, and zero order correlations between self reports and collateral reports of PFW and SWB.

Variables	Self-reports		Collateral-reports		Convergence (r)	n
	M	SD	M	SD		
PERMA	5.28	1.10	5.11	1.10	0.71**	213
Positive emotions	5.19	1.28	5.12	1.31	0.61**	213
Engagement	5.29	1.19	5.14	1.22	0.71**	213
Relationships	5.13	1.22	5.08	1.23	0.55**	
Meaning	5.34	1.34	5.08	1.24	0.56**	215
Accomplishment	5.44	1.15	5.13	1.27	0.58**	214
Positive Functioning (PERMA + 4)	5.19	1.03	5.07	1.16	0.73**	213
Physical Health	5.31	1.14	5.10	1.18	0.64**	214
Positive Mindset	5.30	1.23	5.10	1.24	0.64**	214
Work Environment	4.89	1.28	4.93	1.25	0.58**	214
Economic Security	4.87	1.48	4.93	1.28	0.53**	214
Subjective Well-Being	5.10	1.26	4.97	1.23	0.58**	212

Convergence indicates Pearson correlation coefficients between self-reports and collateral-reports for each of the study variables** = $p < .01$.

Table 2. Correlations of self-reports and collateral-reports of SWB with self-reports of PERMA and positive functioning at work.

Self-reports	Self-reports SWB	Collateral-reports SWB
PERMA	0.75**	0.64**
Positive emotions	0.71**	0.59**
Engagement	0.67**	0.66**
Relationships	0.66**	0.54**
Meaning	0.59**	0.48**
Accomplishment	0.69**	0.58**
Positive Functioning	0.80**	0.66**
Health	0.76**	0.57**
Economic security	0.59**	0.45**
Work environment	0.63**	0.49**
Positive mindset	0.66**	0.62**

$N = 212$; Convergence indicates Pearson correlation coefficients between self-reports and collateral-reports for each of the study variables; ** = $p < .01$.

Table 3. Regression analysis for self-reported PERMA Predicting self-reported and collateral-reports SWB.

	Self-Reported SWB		Collateral-Reported SWB	
	b	95% CI	b	95% CI
Intercept	0.88**	[0.21, 1.55]	1.57**	[0.77, 2.36]
Self-Reported PERMA	0.84**	[0.75, 0.95]	0.70**	[0.58, 0.83]
Gender				
Male vs. Female	0.19	[-.03, 0.42]	0.03	[-.23, 0.31]
Age	-0.01**	[-.02, -0.00]	-0.01**	[-.02, -0.00]
Income				
Less than 25 k vs. 50-75 k	0.05	[-0.42, 0.54]	0.08	[-0.51, 0.67]
75-99 vs. 50-75 k	0.24	[-0.10, 0.58]	0.10	[-0.29, 0.51]
100-150 k vs. 50-75 k	0.14	[-0.18, 0.48]	0.24	[-0.15, 0.64]
150 k+ vs. 50-75 k	0.32*	[-0.00, 0.65]	0.18	[-0.20, 0.57]

** = $p < .01$; * = $p < .05$; Self-Reported SWB (Adjusted $R^2 = 0.57$); Collateral-Reported SWB ($R^2 = 0.40$).

Table 4. Regression analysis for self-reported positive functioning at work predicting self-reported and collateral-reports SWB.

	Self-Reported SWB		Collateral-Reported SWB	
	b	95% CI	b	95% CI
Intercept	0.22	[-0.42, 0.87]	1.15**	[0.33, 1.97]
Positive Functioning	0.96**	[0.86, 1.06]	0.78**	[0.65, 0.91]
Gender				
Male vs. Female	0.11	[-.10, 0.32]	-0.01	[-.28, 0.24]
Age	0.00**	[-.01, -0.00]	-0.00	[-.01, 0.00]
Income				
Less than 25 k vs. 50-75 k	0.19	[-0.25, 0.63]	0.15	[-0.42, 0.74]
75-99 vs. 50-75 k	0.19	[-0.11, 0.51]	0.07	[-0.32, 0.47]
100-150 k vs. 50-75 k	0.07	[-0.22, 0.38]	0.19	[-0.19, 0.57]
150 k+ vs. 50-75 k	0.18	[-0.11, 0.48]	0.08	[-0.30, 0.47]

** = $p < .01$; * = $p < .05$; Self-Reported SWB (Adjusted $R^2 = 0.65$); Collateral-Reported SWB ($R^2 = 0.44$).

Table 5. Regression analysis for collateral PERMA predicting self-reported and collateral-reported SWB.

	Self-Reported SWB		Collateral-Reported SWB	
	<i>b</i>	95% <i>CI</i>	<i>b</i>	95% <i>CI</i>
Intercept	2.19**	[1.41, 2.98]	0.50**	[0.01, 0.98]
PERMA	0.59**	[0.47, 0.70]	0.90**	[0.83, 0.97]
Gender				
Male vs. Female	0.12	[-.15, 0.39]	0.03	[-.13, 0.20]
Age	0.00	[-.01, 0.00]	0.00	[-.01, 0.00]
Income				
Less than 25 k vs. 50–75 k	-0.18	[-0.79, 0.41]	0.09	[-0.28, 0.46]
75–99 vs. 50–75 k	0.39*	[-0.01, 0.81]	0.02	[-0.23, 0.27]
100–150 k vs. 50–75 k	0.11	[-0.29, 0.51]	0.06	[-0.18, 0.31]
150 k+ vs. 50–75 k	0.31	[-0.08, 0.71]	-0.05	[-0.29, 0.19]

** = $p < .01$; * = $p < .05$; Self-Reported SWB (Adjusted $R^2 = 0.39$); Collateral-Reported SWB ($R^2 = 0.77$).

reported SWB. As demonstrated in Table 4, self-reported PFW was a significant predictor for both self-reported PFW and collateral reported SWB ($\beta = .96$, $p < .001$; $\beta = .78$, $p < .001$, respectively). These findings provide support for Hypothesis 2.

Our third hypothesis (Hypothesis 3) stated that collateral-reported PERMA will significantly predict self-reported and collateral-reported Subjective Well-Being. As shown in Table 5, collateral reported PERMA significantly predicted both self-reported SWB and collateral reported SWB ($\beta = .59$, $p < .001$; $\beta = .90$, $p < .001$, respectively). These findings provide support for Hypothesis 4.

Finally, Hypothesis 4 suggested collateral-reported PFW will significantly predict self-reported and collateral-reported SWB. As shown in Table 6 collateral reported PFW significantly predicted both self reported SWB and collateral reported SWB ($\beta = .61$, $p < .001$; $\beta = .93$, $p < .001$, respectively). These findings provide support for Hypothesis 4.

Discussion

Goodman et al. (2018) found that self-reports of PERMA were highly correlated ($>.95$) with self-reports of Subjective Well-being (SWB) in an Mturk sample collected at one point in time. These data lead them to

conclude that PERMA is redundant with SWB and does not yield any insights beyond SWB. The findings of the current study – using self-reports and collateral reports based on knowledgeable co-worker pairs – contradicts some of their claims and for the most part supports Seligman's view that the five PERMA components are better conceptualized as building blocks that predict SWB. The findings also support Seligman's claim that the Goodman et al. (2018) Mturk study design which relied on the sole use of one type of measure (i.e., self-reports) may have led to strongly inflated estimates of the relationships between the PERMA building blocks and well-being.

First, the results of this study show that the 5 PERMA elements were correlated with and predicted SWB when using both self-report (SR) and knowledgeable co-worker collateral reports (CR). For example, self-reported PERMA was significantly correlated with both self-reported and co-worker reported SWB (SR = 0.75; CR = 0.64) as were each of the five building blocks individually including positive emotions (SR = 0.71; CR = 0.59), engagement (SR = 0.67; CR = 0.66), relationships (SR = 0.66; CR = 0.54), meaning (SR = 0.59; CR = 0.48), and accomplishment (SR = 0.69; CR = 0.58) were significantly correlated with SWB. The results of the regression analyses as shown in Table 4 demonstrate

Table 6. Regression analysis for collateral PF-W predicting self-reported and collateral-reported SWB.

	Self-Reported SWB		Collateral-Reported SWB	
	<i>b</i>	95% <i>CI</i>	<i>b</i>	95% <i>CI</i>
Intercept	2.10**	[1.31, 2.89]	0.35	[-0.12, 0.83]
Positive Functioning	0.61**	[0.49, 0.72]	0.93**	[0.86, 1.0]
Gender				
Male vs. Female	0.11	[-.16, 0.38]	0.01	[-.14, 0.18]
Age	0.00	[-.01, 0.00]	0.00	[0.00, 0.00]
Income				
Less than 25 k vs. 50–75 k	-0.22	[-0.83, 0.38]	0.03	[-0.33, 0.40]
75–99 vs. 50–75 k	0.39*	[-0.01, 0.81]	0.02	[-0.22, 0.27]
100–150 k vs. 50–75 k	0.10	[-0.30, 0.50]	0.06	[-0.18, 0.30]
150 k+ vs. 50–75 k	0.30	[-0.09, 0.70]	-0.06	[-0.30, 0.17]

** = $p < .01$; * = $p < .05$; Self-Reported SWB (Adjusted $R^2 = 0.39$); Collateral-Reported SWB ($R^2 = 0.78$).

that PERMA significantly predicted SWB. Taken together, these findings support Hypothesis 1 that self-reported PERMA significantly predicts self-reported and collateral reports of SWB. One important finding to note is the correlation between self-reported PERMA and self-reported SWB was notably lower in this co-worker pair sample compared to the Mturk sample based only on self-reports described in Goodman et al. (2018; 0.75 versus 0.98).

Seligman (2018) made it clear that the original 5 elements of PERMA were not theorized to be exhaustive. Rather, they were proposed as a starting point in the examination of the building blocks of well-being. In this study we examined 4 additional building blocks and hypothesized a total of 9 which we called Positive Functioning at Work (or PERMA+4) would also predict self-reported and collateral reports of SWB (Hypothesis 2). The results revealed even stronger correlations between overall Positive Functioning at Work (PF-W) and SWB (SR = 0.80; CR = 0.66), and the 4 additional building blocks physical health (SR = 0.76; CR = 0.57), economic security (SR = 0.59; CR = 0.45), work environment (SR = .63; CR = 0.49), and mindset (SR = .66; CR = .62). Furthermore, the regression analysis showed that self-reported PF-W predicted 65% of the variance in self-report SWB (Adjusted $R^2 = 0.65$) and 44% in the collateral reports of SWB (Adjusted $R^2 = 0.44$). By comparison PERMA predicted 57% of the variance in the self-reports of SWB (Adjusted $R^2 = 0.57$) and 40% of variance in the collateral reports of SWB.

Maybe more impressively, co-worker reports of PERMA and PF-W were also highly correlated with and predicted self-reports and co-worker reports of SWB, thus supporting Hypotheses 3 & 4. Table 5 revealed that co-worker reports of PERMA predicted 39% of the variance in self-reported SWB (Adjusted $R^2 = 0.39$) and 77% of the variance in collateral reports of SWB (Adjusted $R^2 = 0.77$). Similarly, Table 5 revealed that co-worker reports of PF-W predicted 39% of the variance in self-reported SWB (Adjusted $R^2 = 0.39$) and 78% of the variance in collateral reports of SWB (Adjusted $R^2 = 0.78$). While these analyses illustrate the power of shared method variance or mono-method bias in that the variance accounted for estimates are much higher when both variables are measured by same method (in this example coworker reports), they also reveal co-worker reports of PERMA and PF-W are robust enough to predict 39% of the variance in self-reports of SWB.

Implications

Many studies in positive psychology and of the PERMA building blocks have been limited to one source of

measurement which has been most often self-reports. As was noted earlier, it has been estimated that nearly 70% of all peer-reviewed empirical studies of positive psychology topics are based solely on self-report measures (Ackerman et al., 2018). This study illustrates the value of breaking that norm and examining the relationships between positive psychology constructs like PERMA, PF-W, and SWB with at least two sources of data on the same construct. Measuring a construct with two or more credible sources of information (in this study self and knowledgeable co-worker reports) helps us rule out the serious threat of common method variance being largely accountable for our results (see Ackerman et al., 2018; Donaldson & Grant-Vallone, 2002). One important implication of this study is that it verifies that the relationships between some (hopefully many) positive psychology constructs (like the ones used in this study) are still highly predictive when your design allows you to examine the possibility that mono-method bias alone could account for statistically significant findings.

Another important implication of this study is that it confirms several of Seligman's theoretical claims about PERMA (Seligman, 2011, 2018). It provides evidence that the PERMA building blocks predict SWB, and that previous findings based solely on self-reports were replicated when collateral reports were used. Furthermore, it provides some evidence that the original 5 building blocks are not exhaustive. The additional 4 building blocks explored in this workplace study were also found to be correlated with SWB and add important variance to its prediction. Finally, the PF-W or PERMA+4 framework offers 9 areas where positive psychology interventions (PPIs) can be focused. One possible application of this framework is needs assessment. That is, learning how well people in general, workers, leaders and the like are doing on these 9 building blocks can help guide the development of effective PPIs (see Donaldson, Cabrera, & Gaffaney, under review).

Conclusion

One important strength and contribution of this paper is that it one of the first empirical studies to date to test the PERMA building blocks beyond solely using self-reports. As such, it provides more evidence and insight for understanding the debate in the *Journal of Positive Psychology* between Goodman et al. (2018) and Seligman (2018). It also extends the understanding that the 5 PERMA building blocks are not exhaustive and sheds light on 4 additional building blocks of well-being to consider, especially in future positive psychology studies in the workplace. However, it is important to point out that like

the Goodman et al.'s (2018) analysis of PERMA, this study is based on one cross-sectional sample and that future studies of PERMA and the building blocks of well-being are needed to understand the generalizability of our findings. It is our hope that the innovative knowledgeable co-worker pair design we employed will inspire future positive psychology and well-being researchers to try to understand and control for self-report and mono-method bias in their research designs.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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