



Development of the MINDS Client Profile Checklist for Determining the Vocational Competency of Adults with Intellectual and Developmental Disabilities

Vimallan Manokara¹ · Manisha Kishore¹ · Yvonne Lee Pei Yi¹

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Abstract

There is a need to systematically assess vocational competency of adults with intellectual and developmental disabilities (IDD) according to the level of support they require. The present study reports on the development of the Client Profile Checklist (CPC) to assess vocational competency of adults with IDD. The 38 items that were selected from empirical literature and interviews with clinical staff were rated by training officers for 969 18 to 52-year-old trainees with IDD from low, medium, and high support level vocational training tracks. Factor analyses, multivariate analyses, ROC analyses, and reliability analyses were conducted to examine internal consistency, reliability, validity, and factor structure. Factor analyses yielded a conceptually acceptable 5-factor structure with 36 items accounting for 40.1% of the variance and with the internal consistencies of the subscales ranging from .52 to .81 (total items $\alpha = .85$). The CPC total scores significantly differed across the three support levels. Cutoff scores for each track were also identified. In addition, inter-rater and test-retest reliabilities were high at .80 and .92, respectively. The preliminary results suggest that the CPC may be a useful tool for assessing vocational competency of adults with IDD according to the level of support they require.

Keywords Client profile checklist (CPC) · Rating scale · Vocational · Competency · Intellectual disability · Employment · Support · Training

Introduction

Intellectual disability is characterized by deficits both in intellectual and adaptive functioning, which represent skills required for daily living at an age-appropriate level of behavior, such as communication, social skills, personal independence in home or community settings, and school or work functioning (American Association on Intellectual and Developmental Disabilities 2013; Harris and Greenspan 2016). These limitations must occur during the developmental period, i.e., be evident before the age of 18 years. According to the DSM-V (American Psychiatric Association [APA] 2013), an intelligence quotient (IQ) test score of below 70 on a standardized and

culturally appropriate test generally indicates a significant cognitive deficit.

Employment is a crucial component in the life of a person with intellectual and developmental disability (IDD). Hall (2010) found that at a productive age, social exclusion of people with IDD is motivated by the lack of paid employment. In the UK, supported employment is regarded as a successful model for people with IDD (Beyer et al. 2010). Bayer et al. reported that people with IDD in supported employment presented with higher quality of life than those who were in day activity centers.

Although international policy shifts over the past two decades have pointed towards a focus on open employment for individuals with disabilities, unemployment of this group continues as a pressing public policy concern. Current literature suggests that only 28% of adults with disabilities are in open employment, compared with 70% of those without disabilities (Timmons et al. 2011). This figure is slightly lower for individuals with IDD in particular. For example, only 26% of individuals with IDD supported by disability organizations

✉ Vimallan Manokara
vimallan.hq@minds.org.sg

¹ MINDS, Singapore, Singapore

worked in open employment (Metzel et al. 2007). Concurrently, however, there is a growing number of adults with IDD in sheltered workshops (Mank et al. 2003; Winsor and Butterworth 2008). For every individual in open employment, there are three in sheltered workshops (Migliore et al. 2008). While it is important to develop strategies for increasing the number of adults with IDD in open employment, in the shorter term, it is important to examine ways how they can be better supported in sheltered workshops and optimize the quality of vocational training so that more of them can transition to open employment.

There is a lack of studies on employment for people with IDD in Singapore. Persons with IDD above the age of 18 years who are ready for work are either employed within sheltered workshops or open employment settings, depending on their level of vocational competency and work readiness. In Singapore, adults with ID are predominantly in a sheltered workshop model of employment. Movement for the Intellectually Disabled of Singapore (MINDS) is a large service provider of services to people with IDD in Singapore, with a range of services that cuts across the lifespan for persons with moderate to severe levels of intellectual disability. MINDS operates three Employment Development Centres (EDCs) which provide vocational training for adults with IDD. The function of the EDC is akin to sheltered workshops. The EDCs use a three-track vocational system to better support trainees according to their abilities and needs. These include the Social Enterprise (SE), Sheltered Workshop (SW), and Training and Development (T&D) tracks for trainees with minimal, moderate, and high levels of support needs, respectively. The level of adaptive or work readiness skills a person possesses is considered to be correlated to the type of employment received (i.e., sheltered, supported, competitive) (Stephens et al. 2003) and level of support required (Becker 2005).

Vocational training is provided within the EDCs. The placement of trainees in each vocational track within the EDC was initially based on the observations and opinions of direct care staff (known as “training officers”) and a team of allied health professionals (AHPs) including occupational therapist, social worker, and psychologist. This method of assessment presented a number of issues. As opinions are subjective, different assessors could have differing recommendations on the placement of the same trainee. Clearly, such inconsistency could result in the erroneous placement of trainees in a track unsuitable for their abilities and needs. Furthermore, an underlying issue was that each assessor could have had a different understanding of what constitutes a person’s work readiness or level of support need, which is what separated each track. Hence, the requirements of what made a trainee suitable or unsuitable for a certain track were unclear and subjectively defined. With no objective method of

assessment and placement, there was also difficulty in tracking trainee progress in a consistent manner.

Given the lack of a structure in the assessment of a trainee’s vocational competency and placement, there is a need for a method of assessment that satisfies a few criteria. The assessment tool needs to be relevant to the general profile of EDC trainees and the EDC setting has to be able to clearly define the cutoff requirements for the three vocational tracks and needs to more objectively assess trainees’ vocational competency within the EDC setting so that it subsequently enables placement of EDC trainees into the most suitable track. This assessment would have to take into consideration the level of support each trainee requires and aspects of work readiness, such as social and communication skills, emotion regulation skills, and basic adaptive living skills. Studies have shown that information collected from objective vocational assessment tools can be used effectively for individualized education planning, program building, and transition planning (Ellis et al. 1987). Hence, the selected method of assessment should also aid in the development of programs specifically created for the trainees in each track according to the level of support they require. It would also be important for the instrument to be aligned to the International Classification of Functioning (ICF). For example, Escorpizo et al. (2011) found a multitude of functioning items within the ICF which are related to successful vocational rehabilitation.

Generally, there is a view that people hold low expectations of how much people with IDD can achieve, i.e., there is a tendency to underestimate their capabilities (Hananel 2014; McGrew and Evans 2004; Special Olympics 2003). Even parents, educators, and personnel in helping professions may have low expectations of individuals with disabilities (Pfeiffer et al. 2003; Sanders 2006). Unfortunately, such negative attitudes can lead to lower self-esteem of the individual with the disability and result in a life-long struggle to reach their full potential (Sanders 2006). This can also affect their employment opportunities.

Vocational training facilitates the inclusion of people with IDD by increasing their likelihood of integrating in the community (Myklebust 2013). Also, aside from developing their work-related skills, effective vocational training has positive behavioral and social effects that result in increased quality of life of persons with IDD (Buntix and Schalock 2010; Timmons et al. 2011). A further benefit of vocational training is that it offers the possibility of overcoming the problems resulting from poor qualifications in and little knowledge of modern technology, in as much as it emphasizes practical learning, corresponding to the adaptive skills available to the individuals (Kocman and Weber 2016).

In order to ascertain the type and extent of support that people with IDD need in their vocational training within sheltered workshops, it is pertinent to accurately assess their current level of vocational competency so that individualized and

optimum training support can be given to them during their vocational training. The key to vocational training is to systematically assess and identify key areas for improvement and to refine the skills they need in order to develop skills for successful employment (Verdugo and Bermejo 2009). However, relying on purely subjective judgment to assess vocational competency of persons with IDD might tend to result in a lower-than-accurate estimate of their capabilities, which would disadvantage their vocational opportunities. Hence, the use of appropriate assessment tools is crucial for this purpose.

However, there are a limited number of existing instruments that are used internationally for assessing the vocational competency and job suitability of persons with IDD within sheltered workshop settings. The Becker Work Adjustment Profile-2 (BWAP-2; Becker 2005) is one such tool. The BWAP-2 was created to measure the vocational competency of people with disabilities in their work environments and used to identify areas of concern and work supports needed (Becker 2005). There are items in the BWAP-2 that may not be applicable in the Singapore context for adults with IDD. For example, the instrument has items that assess banking, budgeting, money handling tasks as well as the ability to multiply and divide correctly. However, in Singapore, for many job settings where people with IDD are employed, these might not be necessary skills.

The AAMR Adaptive Behavior Scale—Residential and Community (Nihira et al. 1993) and the Vineland Adaptive Behavior Scale-II (Sparrow et al. 2005) are other examples of instruments that have been used within the sheltered workshop setting. While these two scales measure a broad range of adaptive skills and behaviors, they do not assess vocational competency and their validity for the purpose of vocational training within sheltered workshops is questionable. For example, for placement of a person in a particular vocational track within the EDC, it is not necessary to acquire detailed information about the person's activities of daily living or behavioral background as found in the two scales. The lack of specific focus on vocational skills and performance domains relevant to a sheltered workshop setting indicates that these tools are not appropriate for assessing vocational competency of persons with IDD in the EDCs. The Supports Intensity Scale (Thompson et al. 2004) is a standardized measure used to evaluate an individual's support needs across seven life activity domains, as well as to identify exceptional medical and behavioral support needs. However, as with the BWAP-2, it may not be suitable for purposes of assessing vocational competency specifically for determining training goals and vocational support.

Furthermore, these tools have assessment norms based on adults with IDD in the USA and might not be entirely relevant to Singapore's cultural context. While this does not invalidate the general usefulness of these tools, it is important to be cautious in relying on tools that were not designed for the

purpose of assessing vocational competency within the sheltered workshop setting. Thus, there is a need to develop a vocational assessment tool suitable for the purposes of the MINDS EDC setting and track system that is valid and reliable within the Singapore context.

The aim of the present study was to develop a valid and reliable rating scale that could clearly differentiate the three EDC vocational tracks, identify the key work abilities and support needs of EDC trainees, and place them objectively in one of the three tracks (i.e., SE, SW, and T&D). The utility of the rating scale would have practical implications in terms of how resources (e.g., manpower and environmental modifications and support) are allocated to better support the trainees, such that they are able to perform to the best of their ability.

Method

Participants

The participants were a sample of 969 trainees from three EDCs using information provided by training officers (TOs). This was the total number of persons with IDD receiving vocational training in MINDS EDCs. All trainees had been diagnosed with intellectual disability based on their performance on standardized intelligence tests as well as standardized adaptive behavior assessments. Informants had to have worked with the trainee for a minimum of 6 months. Trainees had an age range of between 18 to 52 years and an average age of 31.8 years.

Procedure

MINDS' psychologists and occupational therapists from the three EDCs met and compiled a list of 38 items that, based on their experience and knowledge, as well as existing literature, measured the trainee's overall functioning relevant to work. The 38 items were related to the following areas of functioning relevant to a client's performance in a work setting: activities of daily living (ADL), sexuality awareness, vocational skills, emotional regulation, leisure and recreation, social and communication skills, adaptive behavior, and help seeking. The 38-item rating scale was called the Client Profile Checklist (CPC).

The 25 interviewers were 3rd and 4th year psychology students from the local university who were attached to MINDS for a 6-week research internship. Part of the internship involved a training phase during which interviewers were trained to administer the CPC. Following training, each interviewer was attached to a production unit within the EDC and administered the CPC to the training officer who acted as informants for the trainees from that particular unit. For each

trainee, there was one training officer who provided information about the trainee. Explanatory notes and examples were developed for all items to ensure clarity of items so that both the interviewer and interviewee had similar understanding. The interviewer adhered closely to the notes. The ratings on all the items formed the composite vocational competency score of the trainee.

Data Analyses

To determine the number of subdomains of vocational competency and to establish a clear factor structure, first, a parallel analysis and then an exploratory factor analysis was undertaken. Next, internal consistencies of each subdomain were established. Once a clear factor structure with acceptable internal consistencies were obtained, multivariate analyses (MANOVA) was undertaken to determine if there were significant differences across the individual domains and the three vocational tracks, as well as to see if the CPC could serve its purpose of differentiating a trainee according to his/her vocational competency and support needs level. Then, ROC analysis was undertaken to determine the cutoff score for each vocational track. Lastly, inter-rater and test-retest reliabilities were established. Inter-rater scoring was done by a psychologist administering the CPC on the same client at the same time as the psychology intern. Test-retest scoring was done at a 1-month interval.

Results

Parallel analysis was first performed to decide on the optimum number of factors to retain. As shown in Table 1, the value of Real data remained higher than the value of Random data up to Component 9, where its value became less than the value of Random data. Hence, we retained eight factors as it is up to Component 8 that Real data value remained higher than Random data.

Internal consistencies of each of the eight subscales were identified. As there were three factors with only two items and four factors with internal consistencies of below .60, the eight-factor structure obtained by parallel analysis was not stable enough. Hence, there was a need to run the factor analysis again. This time, factors were selected from the scree plot,

Table 1 Parallel analysis

Component	Real data	Random data
1	8.159	1.483
2	3.571	1.436
8	1.304	1.276
9	1.217	1.254

which indicated five factors. The scree plot is shown in Fig. 1. Five factors were specified with principal component extraction and direct oblimin rotation. Items with loadings of less than .30 were omitted.

The results showed a clear and stable five-factor model with 36 items that was generally statistically and theoretically sound. The five factors were named: Vocational Skills, Emotional Regulation Skills, Social and Communication Skills, Activities of Daily Living, and Sexuality Awareness. Table 2 shows the items that were included in each of the five factors, and factor scores.

The internal consistencies were .80 for Vocational Skills, .81 for Emotional Regulation Skills, .76 for Social and Communication Skills, .53 for Activities of Daily Living, and .64 for Sexuality Awareness. All five factors had at least three items and acceptable internal consistencies except the Activities of Daily Living factor. The Cronbach's alpha for the total scale was .85.

Next, multivariate analyses were conducted to identify differences in scores across each of the five factors and three vocational tracks. Significant multivariate effects were found (Pillai's trace = .73, multivariate $F(10, 966) = 118.86$, $p < .001$). As seen in Tables 3 and 4, test of between-subjects effects showed that total scores as well as individual factor scores significantly differed among the three vocational tracks.

Receiver operating curve (ROC) analyses were also conducted to derive cutoff scores for the different tracks. Scores below 99 would indicate the trainee to be placed in the T&D track while scores between 99 and 111 would place the trainee in the S/W track, and scores above 111 would indicate that the trainee be placed in the SE track. Figure 2 shows the ROC plot for difference between the T&D track and the SW track. The area under the curve was .725, indicating that the cutoff score of 99 was a fair cutoff score. Figure 3 shows the ROC plot for difference between the SW track and SE Enterprise track. The area under the curve was .75, indicating that the cutoff score of 111 was a good cutoff score.

Test-retest reliability was very high, $r = .92$, $p < .01$. Hence, there is a 92% probability that a client who falls in a particular track at Time 1 would fall in the same track at Time 2. Inter-rater reliability was high, $K = .80$, $p < .001$. This meant that any two persons who administer the CPC on the same client are likely to obtain the same vocational track for the client 80% of the time.

Discussion

The results indicate that the CPC is able to differentiate total scores as well as individual domain scores significantly across the three vocational tracks. This implies that the

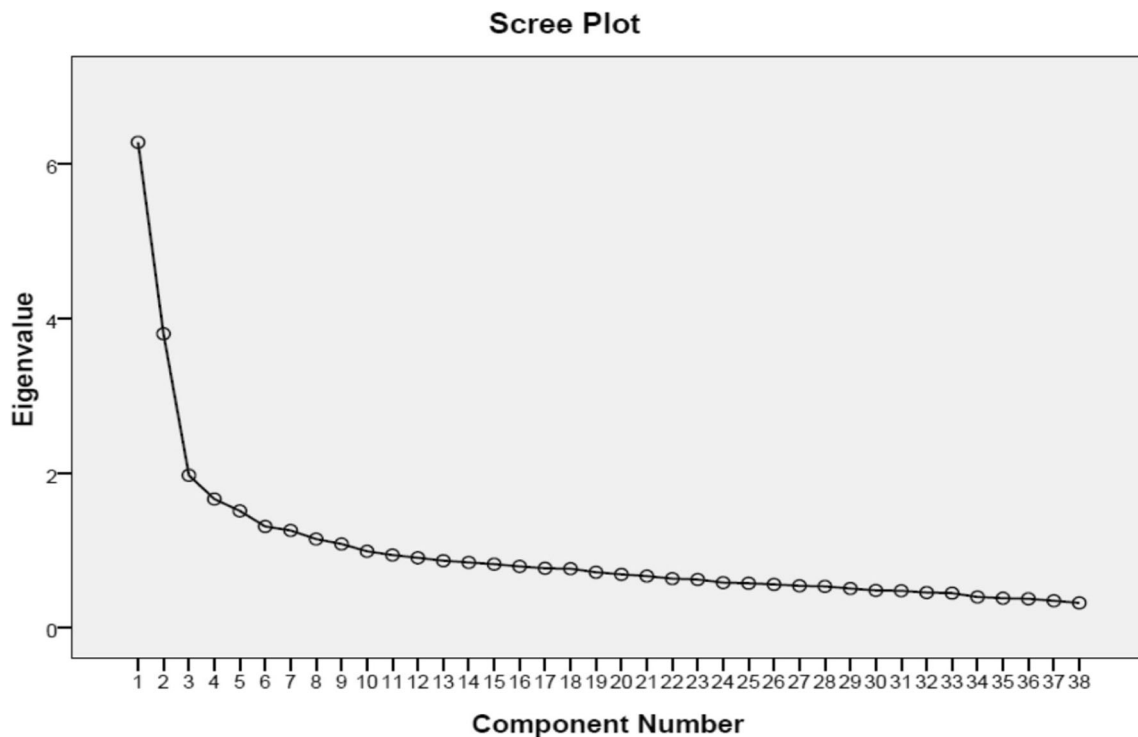


Fig. 1 Scree plot

CPC could be a useful tool in systematically assessing the overall functioning level relevant to work and vocational competency of trainees with IDD. The client's composite score on the CPC can also potentially indicate how much support he/she would need in terms of the three different vocational tracks. More capable trainees who require minimal support are usually placed in the SE track, trainees who require moderate support are placed in the SW track, and those who require high-level support are placed in the T&D track. This allows resources, such as manpower and environmental resources, to be channeled accordingly to better support the client so that the client is able to achieve his/her maximum potential in the work tasks.

Although there are existing tools to measure adaptive behavior, health status, and work readiness in adults with IDD, there is no tool which measures vocational competency in terms of matching suitable vocational tracks for trainees according to the level of support they require (Riemsma et al. 2001). The development of the CPC is therefore a first step in determining trainee suitability in the three vocational tracks at the EDC. The CPC could potentially assess trainee progress or improvement following vocational training.

Aside from having sound psychometric properties, the CPC's items are relevant to the local job market in Singapore and, thus, are relevant to the local context. As such, it is a useful tool in the Asian population compared to other tools which have been normed in western countries. In addition, the CPC uses a 3-point Likert scale and

has clear explanations and examples for each item, which makes it easier for direct care staff to understand and answer the items.

According to Thompson et al. (2009), in order for support need assessment tools to be of value, they should be easily placed into practice and used by professionals, non-professionals, and stakeholders with a wide range of skills. They should also produce consistent results and outcomes when used across service areas and regions, be person centered, and provide accessible and understandable information to a wide range of stakeholders. It is pertinent for support need assessment tools to identify the support needs of people with complex and challenging conditions, and generate results that are applicable to decision making across a wide range of issues. In addition, they should be capable of being integrated in the support planning process of the individuals receiving support. It is encouraging that the CPC demonstrates promise in fulfilling these criteria.

The importance of systematically and objectively assessing vocational competency to inform vocational training cannot be underestimated. It is crucial in aligning practice with person-centered planning. Internationally, person-centered planning has been increasingly adopted in intellectual disability services. For example, in the United Kingdom (UK), it has assumed central focus in the 2001 White Paper—Valuing people. The White Paper identifies person-centered planning as central to delivering the UK government's four key principles (rights, independence,

Table 2 Factors items and factor loadings

	Factor				
	1. Vocational Skills	2. Emotional Regulation	3. Social and Communication Skills	4. Activities of Daily Living	5. Sexuality Awareness
1. Resumes activity without assistance or prompts after breaks or interruptions	.670				
2. Performs a given task according to requirements	.506				
3. Check own work and corrects mistakes	.451				
4. Accepts feedback constructively and demonstrates effort to change		.328			
5. Works at faster rate when requested	.539				
6. Continues to work whether staff is present or not	.805				
7. Demonstrates energy and physical stamina for work	.635				
8. Initiates another task upon completing a given task	.485				
9. Displays good work etiquette	.658				
10. Seeks attention appropriately from staff		.358			
11. Able to stay on task for at least 20 mins without distractions.	.625				
12. Is generally calm and composed in most work situations.		.629			
13. Engages in behaviors that are not excessively attention seeking.		.526			
14. Generally behaves in ways that do not interfere significantly with one's daily living.					
15. Speaks in an un-offensive and non-aggressive manner.		.706			
16. Demonstrates non-physical aggressive behaviors.		.495			
17. Demonstrates behaviors that are not emotionally aggressive towards others.		.699			
18. Demonstrates non-disruptive behaviors towards self/others.		.538			
19. Polite towards others		.682			
20. Is generally continent of urine and bowel movement				.301	
21. Maintains personal hygiene after using toilet				.743	
22. Bathes and changes in clean clothes everyday				.603	
23. Keep hands clean				.573	
24. Takes care of hair cleanliness				.471	
25. Expresses self in clear manner through speech/gestures			.641		
26. Initiates communication			.758		
27. Listens to others and takes turns during communication		.502			
28. Client understands when others communicate to him/her			.431		
29. Generally speaks coherently and in non-hurried manner			.435		
30. Demonstrates good touch					-.760
31. Conducts self appropriately					-.750
32. Has no current/history of inappropriate sexual behavior towards self or others					-.594
33. Seeks help when upset or when others disturb them			.691		
34. Notifies and seeks help when in times of minor pain and injuries/accidents that may involve self or others			.713		
35. Actively participates in leisure activities organized by caregivers/family/TOs			.556		
36. Knows how to engage in recreation or request for activities in their free time.			.471		

choice, and inclusion) and a high priority for management attention and resources (Mansell and Beadle-Brown 2004).

Pertinent challenges for person-centered planning is the lack of knowledge and awareness of staff as to the type

Table 3 Difference in total scores across the five factors

Multivariate analyses						
Track	Vocational Skills	7004.067	2	3502.034	454.336	.000
	Emotional Regulation Skills	3671.861	2	1835.930	224.513	.000
	Social and Communication Skills	4231.806	2	2115.903	272.310	.000
	ADL	120.525	2	60.263	75.125	.000
	Sexuality Management Skills	77.712	2	36.856	34.546	.000

and extent of support that needs to be given as well as the setting of appropriate goals for individuals with IDD (Mansell and Beadle-Brown 2004). These issues are not different from what staff in MINDS EDCs face. Hence, the CPC allows staff to set vocational training goals as well as individualize vocational support and training.

Limitations and Future Research Directions

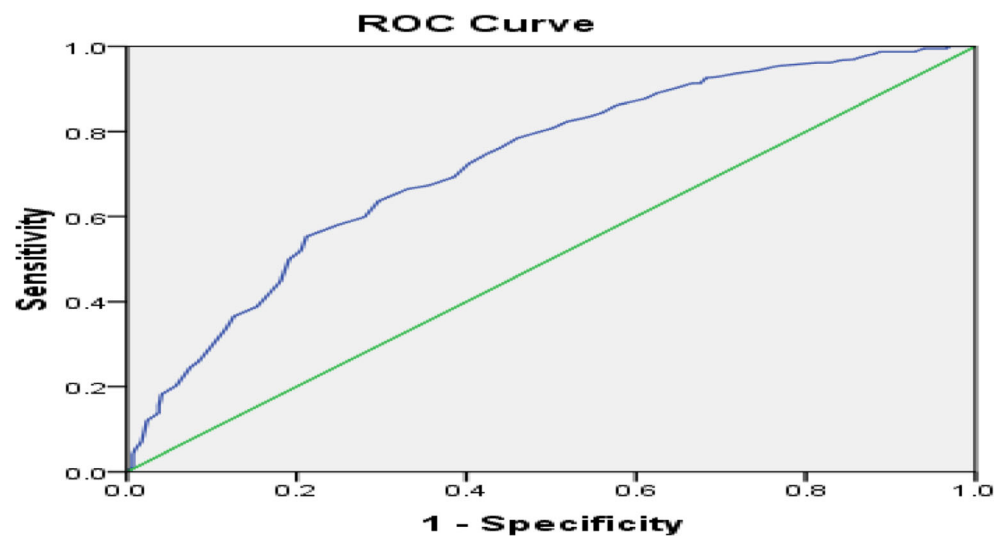
The CPC is not without limitations. One limitation is that the cutoff scores separating the vocational tracks have a small difference. A large sample size may have created a statistical significance in the cutoff scores of < 99, 99–111, and > 111 for

Table 4 Difference in scores across vocational tracks and individual factors

Dependent variable	(I) Track	(J) Track	Mean difference (I–J)	Std. error	Sig	95% Confidence interval	
						Lower bound	Upper bound
Factor 1 Vocational Skills	1	2	– 5.2243*	.21072	.000	– 5.7189	– 4.7296
		3	– 7.6730*	.27885	.000	– 8.3275	– 7.0184
	2	1	5.2243*	.21072	.000	4.7296	5.7189
		3	– 2.4487*	.24744	.000	– 3.0295	– 1.8679
	3	1	7.6730*	.27885	.000	7.0184	8.3275
		2	2.4487*	.24744	.000	1.8679	3.0295
Factor 2 Emotion Regulation Skills	1	2	– 3.8867*	.21705	.000	– 4.3962	– 3.3773
		3	– 5.4490*	.28721	.000	– 6.1232	– 4.7748
	2	1	3.8867*	.21705	.000	3.3773	4.3962
		3	– 1.5623*	.25486	.000	– 2.1605	– .9640
	3	1	5.4490*	.28721	.000	4.7748	6.1232
		2	1.5623*	.25486	.000	.9640	2.1605
Factor 3 Social Communication Skills	1	2	– 3.6126*	.21157	.000	– 4.1092	– 3.1159
		3	– 6.2870*	.27997	.000	– 6.9441	– 5.6298
	2	1	3.6126*	.21157	.000	3.1159	4.1092
		3	– 2.6744*	.24844	.000	– 3.2576	– 2.0912
	3	1	6.2870*	.27997	.000	5.6298	6.9441
		2	2.6744*	.24844	.000	2.0912	3.2576
Factor 4 ADL	1	2	– .7253	.06798	.000	– .8848	– .5657
		3	– .9618	.08996	.000	– 1.1730	– .7507
	2	1	.7253*	.06798	.000	.5657	.8848
		3	– .2366*	.07982	.009	.4239	– .0492
	3	1	.9618*	.08996	.000	.7507	1.1730
		2	.2366*	.07982	.000	.0492	.4239
Factor 5 Sexuality Management Skills	1	2	– .5269*	.08050	.000	– .7159	– .3380
		3	– .8281*	.10652	.000	– 1.0781	– .5781
	2	1	.5269*	.08050	.000	.3380	.7159
		3	– .3012*	.09452	.004	– .5230	– .0793
	3	1	.8281*	.10652	.000	.5781	1.0781
		2	.3012*	.09452	.004	.0793	.5230

The asterisks indicate significance at the .01 level

Fig. 2 ROC plot for difference between the T&D track and the SW track



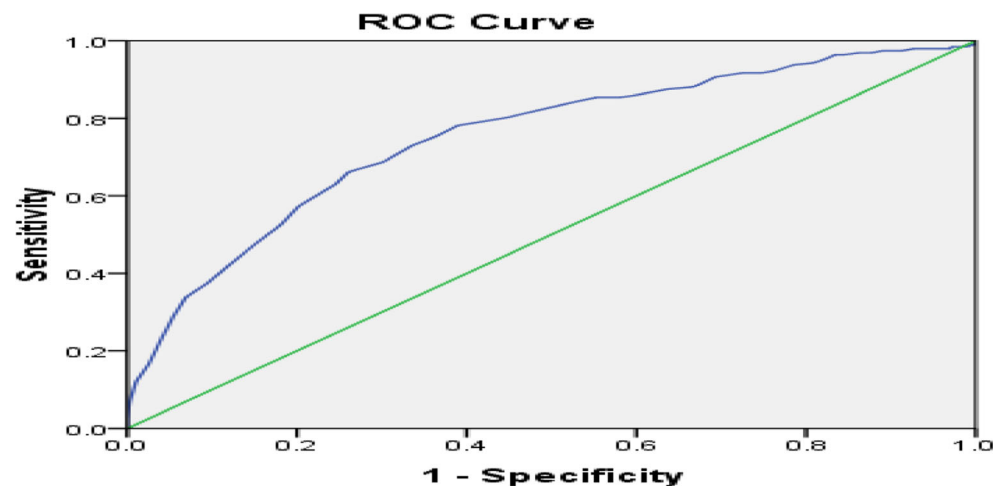
the grouping of clients into T&D, SW, and SE tracks. But, in practice, the differences may not be meaningful. The mean differences between the factors and tracks are small. That is, clients are placed into the three tracks based on few differences in level of ability/skills. To address this issue, we could calculate the magnitude of the effect sizes by identifying the differences in the mean of each track. This would then allow us to determine if the small differences in cutoff scores can be interpreted meaningfully. Also, it would be useful to add more advanced items for each factor that are able to more clearly differentiate clients from the different tracks. This would potentially increase the mean differences between each track as well as among the factors.

Moving forward, there are a few ways the CPC could be further strengthened. First, it would be necessary to perform a confirmatory factor analysis on a different sample to confirm the five-factor model of the CPC. Second, although the CPC appears to have good face validity, it would be useful to test its concurrent and predictive validity. Escorpizo et al. (2011) found a multitude of functioning items within the ICF which

were related to successful vocational rehabilitation. Among the items highlighted were toileting and appropriate dressing which seemed to correlate with items in the activities of daily living domain of the CPC. There was also an item on maintaining interpersonal relationships which appears to be similar to the CPC's social skills domain. Hence, there appears to be some basis to suggest that these items on both the ICF and the CPC are theoretically related and should be measuring the same constructs.

Finally, it would be good to conduct further correlational studies with those functioning items of the ICF to assess the concurrent validity of the domains of the CPC. Another tool that can be used to establish concurrent validity for the CPC would be the Becker's Work Adjustment Profile-2 (BWAP-2), which is an established tool assessing work readiness and has subdomains that are similar to the CPC. Predictive validity of the CPC could be explored by looking at outcome measures such as sustainability in supported and open employment of clients who were identified to be in the SE track by the CPC.

Fig. 3 ROC plot for difference between the SW track and SE track



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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in this study involving humans were in accordance with the ethical standards of the institution at which the studies were conducted.

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

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