Образац **4.**

Факултет Фармацеутски

УНИВЕРЗИТЕТ У БЕОГРАДУ

01 број
(Број захтева)

Већу научних области медицинских наука
(Назив већа научне области коме се захтев упућује)

20.06.2024.
(Датум)

З А Х Т Е В

за давање сагласности на одлук**е** о усвајању извештаја Комисије за оцену докторске дисертације и о именовању комисије за одбрану

Молимо да, сходно члану 47. ст. 5. тач. 4. Статута Универзитета у Београду ("Гласник Универзитет", број 186/15-пречишћени текст и 189/16), дате сагласност на одлуку о усвајању извештаја Комисије за оцену докторске дисертације:

КАНДИДАТ **ЛЕВИЋ (МИРОСЛАВ) МАРИЈА**
(име, име једног од родитеља и презиме)

студент докторских студија на студијском програму Фармацеутске науке

пријавио је докторску дисертацију под називом:

„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“

из научне области: СОЦИЈАЛНА ФАРМАЦИЈА И ИСТРАЖИВАЊЕ ФАРМАЦЕУТСКЕ ПРАКСЕ

Универзитет је дана 22.02.2022.године својим актом под бр. 02-01 број 61206-511/2-21 дао сагласност на предлог теме докторске дисертацијекоја је гласила:

„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“

Име и презиме ментора : Проф др. Душанка Крајновић, редовни професор, Универзитет у Београду – Фармацеутски факултет;

Комисија за оцену докторске дисертације именована је на седници одржаној 11.04.2024.године одлуком факултета под бр. 01 бр.898/2 **,** у саставу:

Име и презиме члана комисије	звање	научна област	Установа у којој је запослен

1. Др сци. Наташа Богавац - Станојевић, редовни професор, Универзитет у Београду - Фармацеутски факултет
2. Др сци. Срђан Поповић, редовни професор у пензији, Универзитет у Београду - Медицински факултет
3. Др сци. Александра Јовић - Вранеш, редовни професор, Универзитет у Београду - Медицински факултет
4. Др сци. Валентина Маринковић, редовни професор, Универзитет у Београду - Фармацеутски факултет
5. Др сци. Андријана Милошевић Георгиев, доцент, Универзитет у Београду - Фармацеутски факултет

Напомена**:** уколико је члан Комисије у пензији навести датум пензионисања.

Датум стављања извештаја Комисије и докторске дисертације на увид јавности: 16.05.2024.године.

Наставно-научно веће факултета усвојило је извештај Комисије за оцену докторске дисертације наседници одржаној дана 20.06.2024.године.

Комисија за одбрану докторске дисертације именована је на седници одржаној 11.04.2024.године

одлуком факултета под бр. 01 број 898/2, у саставу:

Име и презиме члана комисије	звање	научна област	Установа у којој је запослен

1. Др сци. Наташа Богавац - Станојевић, редовни професор, Универзитет у Београду - Фармацеутски факултет
2. Др сци. Срђан Поповић, редовни професор у пензији, Универзитет у Београду - Медицински факултет
3. Др сци. Александра Јовић - Вранеш, редовни професор, Универзитет у Београду - Медицински факултет
4. Др сци. Валентина Маринковић, редовни професор, Универзитет у Београду - Фармацеутски факултет
5. Др сци. Андријана Милошевић Георгиев, доцент, Универзитет у Београду - Фармацеутски факултет

Напомена: уколико је члан Комисије у пензији навести датум пензионисања.

ДЕКАН ФАКУЛТЕТА

Прилози:
1. Одлука Наставно-научног већа о усвајању извештаја Комисије за оцену докторске дисертације и одлука о именовању Комисије за одбрану докторске дисертације
2. Извештај Комисије о оцени докторске дисертације
3. Примедбе на извештај Комисије о оцени докторске дисертације (уколико их је било) и мишљење Комисије о примедбама

Напомена: Факултет доставља Универзитету захтев са прилозима у електронској форми и у једном писаном примерку за архиву Универзитета

УНИВЕРЗИТЕТ У БЕОГРАДУ
ФАРМАЦЕУТСКИ ФАКУЛТЕТ
11000 - БЕОГРАД
Ул. Војводе Степе 450.
01. број_____
20.06.2024. године

На основу члана 28. Статута и предлога Комисије за последипломске студије, Наставно-научно веће Универзитета у Београду – Фармацеутског факултета на седници одржаној 20.06.2024. године, донело је

О Д Л У К У

ПРИХВАТА СЕ позитиван извештај Комисије за оцену и одбрану завршене докторске дисертације**,** кандидата **маг.фармације Левић Марија** под насловом: **„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“** и упућује Већу научних области медицинских наука на усвајање, а по добијеној писаној сагласности одобрава јавна одбрана пред Комисијом у саставу:

1. Др сци. Наташа Богавац - Станојевић, редовни професор, Универзитет у Београду - Фармацеутски факултет
2. Др сци. Срђан Поповић, редовни професор у пензији, Универзитет у Београду - Медицински факултет
3. Др сци. Александра Јовић - Вранеш, редовни професор, Универзитет у Београду - Медицински факултет
4. Др сци. Валентина Маринковић, редовни професор, Универзитет у Београду - Фармацеутски факултет
5. Др сци. Андријана Милошевић Георгиев, доцент, Универзитет у Београду - Фармацеутски факултет

Универзитет је дана 22.02.2022.године својим актом бр.: 02-01 бр: 61206-511/2-22 дао сагласност на предлог теме докторске дисертације.

Кандидат маг. фарм. Марија Левић, објавила је резултате из ове докторске дисертације у два рада категорије М21 и једном раду категорије М22 у међународним часописима са СЦИ листе:

1. **Levic M**, Bogavac-Stanojevic N, Ubavic S, Krajnovic D. Pharmacotherapy literacy level andpredictors of low literacy among diabetes mellitus type 2 patients in Serbia. BMC PublicHealth.2023;23(1):1822. https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-16639-y
   IF (2022) = 4,5; *Public, Environmental & Occupational Health* (75/300) M21
2. **Levic M**, Bogavac-Stanojevic N, Krajnovic D. The Instruments Used to Assess HealthLiteracy and Pharmacotherapy Literacy of Diabetes Mellitus Type 2 Patients: A ScopingReview. Front Public Health. 2021;9:1424-1440. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8502961/
   IF (2021) = 6,461; *Public, Environmental & Occupational Health* (39/302) M21

3. **Levic M***, Bogavac-Stanojevic N*, Krajnovic D*. Cross-Cultural Adaptation and Validation of the Functional, Communicative and Critical Health Literacy Instrument (FCCHL-SR) for Diabetic Patients in Serbia. Healthcare (Basel). 2022;10(9):1667. (*equal contribution) https://www.mdpi.com/2227-9032/10/9/1667
IF (2022) = 2,8; *Health Care Sciences & Services* (57/106) M22

Одлуку доставити: именованој, Универзитету, члановима комисије, декану, секретару,продекану за последипломске студије, ментору (Проф др. Душанка Крајновић), Одсеку за наставу и студентска питања, Одсеку за правне и опште послове, пословном секретару и архиви.

ПРЕДСЕДНИК
НАСТАВНО-НАУЧНОГ ВЕЋА
ФАРМАЦЕУТСКОГ
ФАКУЛТЕТА

Проф. др Слађана Шобајић

НАСТАВНО-НАУЧНОМ ВЕЋУ УНИВЕРЗИТЕТА У БЕОГРАДУ – ФАРМАЦЕУТСКОГ ФАКУЛТЕТА

КОМИСИЈИ ЗА ПОСЛЕДИПЛОМСКУ НАСТАВУ – ДОКТОРСКЕ СТУДИЈЕ

На седници Наставно-научног већа Универзитета у Београду – Фармацеутског факултета, одржаној 09.04.2024. године, одлука број 898/1, именовани су чланови Комисије за оцену и одбрану завршене докторске дисертације кандидата маг. фарм. Марије М. Левић, под насловом: **„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“.** Ова докторска теза урађена је под менторством др. сц. Душанке Крајновић, редовног професора, Универзитета у Београду - Фармацеутског факултета.

Чланови комисије за оцену и одбрану докторске дисертације у саставу:

1. Др сц. Наташа Богавац - Станојевић, редовни професор, Универзитет у Београду - Фармацеутски факултет
2. Др сц. Срђан Поповић, редовни професор у пензији, Универзитет у Београду - Медицински факултет
3. Др сц. Александра Јовић - Вранеш, редовни професор, Универзитет у Београду - Медицински факултет
4. Др сц. Валентина Маринковић, редовни професор, Универзитет у Београду - Фармацеутски факултет
5. Доц. др Андријана Милошевић Георгиев, Универзитет у Београду - Фармацеутски факултет

Чланови Комисије су прегледали приложену дисертацију и подносе Наставно-научном већу Универзитета у Београду – Фармацеутског факултета следећи извештај:

ИЗВЕШТАЈ

1. ПРИКАЗ САДРЖАЈА ДОКТОРСКЕ ДИСЕРТАЦИЈЕ

Докторска дисертација под насловом: **„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената**

оболелих од дијабетес мелитуса тип 2“ садржи седам поглавља: 1. Увод, 2. Циљеви, 3. Материјал и методе, 4. Резултати 5. Дискусија, 6. Закључци и 7. Литература. Докторска дисертација укључује сажетак на српском и енглеском језику и садржај докторског рада, биографију кандидата, као и потписане изјаве о ауторству, истоветности штампане и електронске верзије и коришћењу докторске дисертације. Дисертација је написана јасним и прегледним стилом и садржи 17 слика, 32 табеле и 207 литературних навода.

Увод докторске дисертације садржи преглед савремених литературних података о дијабетес мелитусу тип 2, са нагласком на здравствену и фармакотерапијску писменост код ових пацијената. Такође, представљени су разлози намерне и ненамерне неадхеренце према терапији, и њихове повезаности са неадекватном здравственом писмености и ниском фармакотерапијском писмености код ове групе хроничних пацијената. У оквиру поглавља 1.6, дат је детаљан приказ упитника за процену здравствене и фармакотерапијске писмености са предлогом најприкладнијих и најсвеобухватнијих упитника за мерење здравствене писмености код пацијента са дијабетесом. *BRIEF* упитници (*BRIEF screening questions*) имају широк распон мерења, и добра мерна својства, и као такви сматрају се најбољим доступним упитницима за мерење функционалног домена здравствене писмености. Упитник за процену три домена здравствене писмености (функционалног, комуникативног и критичког – *FCCHL, Functional, Communicative and Critical Health Literacy Scale*) испитује шири концепт здравствене писмености, укључујући могућност преузимања, разумевања и коришћења здравствених информација и може се сматрати најпогоднијим инструменатом за мерење здравствене писмености код пацијената са дијабетесом. Оба упитника су брза, једноставна за коришћење и финансијски прихватљива. Такође је приказано да до сада коришћени упитници за процену фармакотерапијске писмености нису нашли своју најбољу примену у овој популацији јер не покривају све димензије и под-димензије концептуалног модела фармакотерапијске писмености, неопходним за коришћење информација о лековима и постизање циљева фармакотерапијске писмености. С тим у вези било је неопходно развити специфичан, објективан упитник за примену у здравственом систему. Такође, представљени су фактори који утичу на неадхеренцу према терапији и који су груписани као: 1) фактори који се односе на самог пацијента, 2) социо-економски фактори, 3) фактори здравственог система и тима здравствених радника 4) фактори у вези са здравственим стањем и 5) фактори у вези са терапијом. Приказана је њихова повезаност са неадекватном здравственом и ниском фармакотерапијском писмености код пацијената са дијабетес мелитусом тип 2.

Циљеви истраживања су јасно дефинисани и подељени на четири целине:

1. Културолошка адаптација и валидација мултидимензионалног упитника за процену здравствене писмености, монодимензионалног упитника за процену функционалне здравствене писмености, упитника за самопроцену узрока неадхеренце и конструкција и валидација специфичног упитника за процену фармакотерапијске писмености код пацијената са дијабетес мелитусом тип 2

2. Процена нивоа укупне здравствене писмености, домена функционалне, комуникативне и критичке здравствене писмености и фармакотерапијске писмености код пацијената са дијабетес мелитусом тип 2

3. Идентификација предиктора (демографске, социо-економске карактеристике пацијента, типа терапије) ниске здравствене писмености и фармакотерапијске писмености код пацијената са дијабетес мелитусом тип 2

4. Истраживање везе између социо-демографских карактеристика, контроле гликемије и типа терапије, као и нивоа здравствене писмености и фармакотерапијске писмености са узроцима неадхеренце према терапији.

У поглављу **Материјал и методе**, наведено је да се ради о студији пресека, која је спроведена у установама на примарном нивоу здравствене заштите. Детаљно су описани избор испитаника у студију, критеријуми за укључивање у студију и критеријуми за искључивање из студије. Објашњени су коришћени инструменти, процедура извођења истраживања, као и потребна минимална величина узорка у свим фазама прве и друге научно-истраживачке студије.

Прва истраживачка студија је подразумевала две фазе, пре-валидациону и валидациону фазу и укључила је све упитнике који су се користили у другој истраживачкој студији. Примењено је пет упитника и то: (1) мултидимензиони упитник за процену здравствене писмености којим се могу проценити домени и укупна здравствена писменост на српском језику – *FCCHL-SR12,* (2) кратки упитнци за брзу процену здравствене писмености – *BRIEF-3* и *BRIEF-4*, (3) упитник за процену фармакотерапијске писмености у популацији дијабетичара (*PTHL-DMT*), (4) Чулигов упитник за процену узрока неадхеренце према прописаној терапији и (5) општи упитник.

У првој пре-валидационој фази прве научно-истраживачке студије, урађена је културолошка и лингвистичка адаптација упитника (1, 2 и 4), конструкција упитника (3) и креирање општег упитника за популацију дијабетичара.

У другој (валидационој) фази прве научно-истраживачке студије извршена је валидација FCCHL-SR упитника, BRIEF-4, PTHL-DM упитника и скале за узроке неадхеренце у оквиру Чуличговог упитника.

Друга истраживачка студија је подразумевала примену валидираних инструмената на узорачкој популацији. Обе истраживачке студије су пратиле неекспериментални дизајн и спроведене су као студије пресека. Узорак су чинили пацијенти оболели од дијабетес мелистуса тип 2, амбулантно лечени у једном великом дому здравља, односно који су своју терапију подизали у једној јавној апотеци у приватном власништву на територији Београда.

Студије су спроведене у складу са Хелсиншком декларацијом и одобрене су од стране етичког комитета за биомедицинска истраживања Фармацеутског факултета Универзитета у Београду и од стране етичких одбора здравствених установа у којима су спроведена

истраживања. Сви испитаници су дали пристанак да учествују у истраживању и да се сви прикупљени подаци могу користити за анализу и публиковање резултата. Детаљно је описана и статистичка анализа података које је поред дескриптивних статистичких метода обухватила и инференцијалну статистику. У оквиру дескриптивне статистике коришћене су фреквенце и средње вредности, као и процентуални удео. У циљу испуњења постављених циљева, резултати су анализирани коришћењем $\chi 2$ теста, студентовог т-теста и ANOVA или њихових непараметарских алтернатива. За процену конструктивне валидности културолошки адаптираних и прилагођених упитника (иницијалне верзије упитника) коришћена је конфирматорна факторска анализа, док је за критеријумску валидност и поузданост тих упитника коришћена линеарна или логистичка регресиона анализа. Униваријантна и мултиваријантна логистичка регресиона анализа примењена је у циљу идентификације повезаности између зависних и независних варијабли (различитих нивоа писмености (укупне HL, домена HL, PTHL) са узроцима неадхеренце и социо-демографским карактеристикама) и утврђивања независних предиктора ниске здравствене и фармакотерапијске писмености.

Резултати и **дискусија** докторске дисертације су прегледно груписани у две главне целине на две научно-истраживачке студије, које прате претходно описане фазе и садрже 6 слика и 27 табела. У овом поглављу су на свеобухватан и јасан начин текстуално и графички приказани оригинални резултати, а дискусија је обухватила анализу и разматрање добијених резултата са критичким осврtом на резултате сличних истраживња.

Закључци докторске дисертације садржи сажето приказане најважније закључке проистекле из резултата истраживања, а који су у складу са претходно постављеним циљевима. Наведене су предности и ограничења истраживања праћена општим закључцима.

У оквиру поглавља **Литература** наведено је 207 референци.

Биографија садржи кратку биографију кандидата.

2. ОПИС ПОСТИГНУТИХ РЕЗУЛТАТА

Први циљ

Културолошка и лингвистичка адаптација *FCCHL-SR12* и *BRIEF-4* (*BRIEF-3*) упитника су спроведене на основу сугестија испитаника да се реше поједине нејасноће и како би се добијене корекције приближиле духу српског језика.

Културолошка и лингвистичка адаптација Чуligовог упитника није захтевала велике измене, анализом повратног превода усаглашених верзија резултирало је очување неизмењеног текста упитника на српском језику, пошто је добро одражавао документ на хрватском језику и усклађен је са стандардима који се користе код ове популације пацијената у Србији.

Конструкција *PTHL-DM* упитника подразумевала је финалну верзију од 15 питања, подељених у 4 фармакотерапијске групе - питања о приступу информацијама (2 питања), разумевању (3 питања), тумачењu информација (4 питања) и коришћењу информација (6 питања).

Код валидационих студија међукласни коефицијенти корелације *(ICC)* били су задовољавајући. За упитник *FCCHL-SR12* вредност је износила 0,77 са 95% интервалима поверења у распону 0,70-0,82. Међутим, ова вредност је варирала за домене: 0,79 (*FHL*), 0,75 (*IHL*) и 0,79 (*CHL*). Вредност *ICC* за *BRIEF-3* и *BRIEF-4* била је 0,65 у распону 0,58–0,71, код *PTHL-DM* израчуната вредност ICC за цео упитник била је 0,97 у опсегу 0,95–0,99, док је код Чулиговог упитника вредност била 0,89 са 95% интервалима поверења у опсегу 0,88-0,89.

Други циљ

У зависности од примењеног инструмента, преваленција неадекватне здравствене писмености је процењена на 42,2% (*FCCHL-SR12* упитник), 36,9% (*BRIEF*-3 упитник) и 33,8% (*BRIEF*-4 упитник). Применом сва три упитника за процену здравствене писмености доказано је да је неадекватна здравствена писменост била чешћа код пацијената са нижим образовањем (*FCCHL-SR12*/p=0,025, *BRIEF-3*/p<0,001, *BRIEF-4*/p=0,001), пацијената који су ретко вежбали (*FCCHL-SR12*/p=0,039, *BRIEF-3*/p=0,005, *BRIEF-4*/p=0,025), и оних који су често конзумирали алкохол (*FCCHL-SR12*/p=0,019, *BRIEF-3*/p=0,001, *BRIEF-4*/p=0,026),

Резултати су показали да само 5% пацијената има висок ниво фармакотерапијске писмености, 33,4% има средњи, док су остали испитаници имали низак ниво фармакотерапијске писмености (62%). Старије године су повезане са нижим нивоом фармакотерапијском писмености (p = 0,038). Пацијенти са једним дететом били су чешћи у групи са високом фармакотерапијском писмености од оних без деце или са двоје и више деце ($\chi2$= 4,47/p=0,001). Пацијенти са ниским степеном образовања (завршена средња школа или ниже) били су заступљенији у групи са ниским нивоом фармакотерапијске писмености ($\chi2$=11,23/p=0,004). Највећи проценат ниско писмених је у групи пацијената који узимају оралне антидијабетике, затим код оних који узимају оралне антидијабетике и инсулин, који су на дијететском режиму и користе само инсулин (65,3%, 54,7%, 50%, 22,2%, редом).

Пацијенти који примењују лек три или више пута дневно показали су виши ниво фармакотерапијске писмености ($\chi2$=6,78/p=0,034) од оних који су узимали лек једном/два пута дневно.

Трећи циљ

Образовање је значајан независни предиктор неадекватне здравствене писмености, што је доказано применом сва три упитника за процену здравствене писмености (*FCCHL-SR12*/p=0,026, *BRIEF-3*/p=0,010, *BRIEF-4*/p=0,012). Високо образовање је било повезано са мањом вероватноћом за неадекватну здравствену писменост пацијената. Ако се упореде независни предиктори за *BRIEF-3* и *BRIEF-4*, може се видети да је предиктор (осим образовања) била старост (p=0,025, p=0,003, редом). Поред тога, број деце је независни предиктор за *BRIEF-3* (p=0,022). Већи број деце и године су повезани са већом вероватноћом недекватне здравствене писмености. Алкохол

је процењен као независни предиктор применом *FCCHL-SR12* упитника (p=0,010). Мања конзумација алкохола повезана је са мањом вероватноћом неадекватне здравствене писмености.

Што се тиче фармакотерапијске писмености пушење је било значајан независни предиктор (p=0,048). Мало интересовање за здравље (p=0,004) и процена здравља као лошег (p=0,021) били су повезани са већом вероватноћом ниске фармакотерапијске писмености. Извор здравствених информација (p=0,001) је такође био независни предиктор, мања вероватноћа за низак ниво фармакотерапијске писмености је добијена ако се савет добије од фармацеута у поређењу са лекарима**.**

Четврти циљ

Резултати су показали значајне статистичке разлике за само 2 од укупно 16 испитиваних узрока/разлога неадхеренце у укупном узорку. Статистички значајно већи је број мушкараца од жена (p=0,011) који су навели несташице лекова као узрок неадхерентности. У групи испитаника са средњим нивом месечних прихода, између 40,000–60,000 RSD било је значајно више оних који су као разлог неадхеренце према терапији навели страх да ће развити зависност од лека (p=0,044) у односу на оне који су имали мања или већа месечна примања.

Добијена је статистички значајна разлика у дистрибуцији одговора између групе испитаника са ниском фармакотерапијском писмености у односу на остале испитанике код узрока "Нисам био код куће" (p=0,021), као и узрока "Спавало ми се када сам требао узети лек" (p=0,033), оба из групе фактора који се односе на самог пацијента.

Резултати показују да није добијена статистички значајна разлика у дистрибуцији одговора између групе испитаника са неадекватном здравственом писмености и целокупног узорка ни за један узрок неадхеренце.

3. УПОРЕДНА АНАЛИЗА РЕЗУЛТАТА ДИСЕРТАЦИЈЕ СА ПОДАЦИМА ИЗ ЛИТЕРАТУРЕ

Први циљ

Слично као и у другим студијама које су користиле *FCCHL* упитник (*Altin* и сар. 2014; *Ishikawa* и сар. 2008; *Fransen* и сар. 2011; *Dwinger* и сар. 2015; *Ousseine* и сар. 2018; *Finbråten* и сар. 2018), резултати су показали да, након превођења и прилагођавања *FCCHL* упитника на српски језик, *FCCHL-SR12* представља валидан упитник, спреман за употребу у нашој земљи и отвара све могућности за изучавање здравствене писмености као и поређење резултата на међународном нивоу. Студија коју су спровели *Ishikawa* и сар. (2008) показала је добру интерну конзистентност (*Cronbach's alpha coefficient*, α=0,84, 0,77 и 0,65, редом по доменима функционална здравствена

писменост, интерактивна/комуникативна здравствена писменост и критичка здравствена писменост) и његова тростепена структура је изгледала обећавајуће за мерење пуног спектра здравствене писмености. Наши резултати се нешто разликују од претходних резултата у Холандији (*Altin* и сар. 2014), који су имали мање задовољавајућу интерну конзистентност комуникативног домена (α=0.63). Како се функционална здравствена писменост дефинише као основне вештине, док комуникативна и критичка здравствена писменост представљају напредне вештине (*Altin* и сар. 2014), коришћење упитника *FCCHL-SR12* може допринети унапређењу бољег разумевање напредних вештина изван разумевања читања и рачунања.

Адаптације које су примењене на оригиналним *BRIEF* упитницима током процеса превођења везане за контекст примарне заштите су у складу са претходним пријављеним у различитим истраживањима (*Schwartz* и сар. 2013; *Mantwill* и сар. 2018). Интерна конзистенција упитника је била добра (α=0,65), претходна студија коју су спровели *Chew* и сар. (2004) мало се разликовала у резултатима са нешто бољом интерном конзистенцијом (α=0,79).

Српска верзија Чуліговог упитника је подвргнута потпуној лингвистичкој процедури валидације (*Fransen* и сар. 2011; *Fransen* и сар. 2014), пре него што је коришћен за испитивање неадхеренце и њених разлога код пацијената са дијабетес мелитусом тип 2. Истраживања о адхерентности се обично фокусирају на баријере са којима се пацијенти суочавају приликом узимања својих лекова. У одговорима на упитник, типичан разлог који пацијенти наводе за неузимање својих лекова укључује заборавност (*Osterberg* и сар. 2005). Ово није неубичајено с обзиром на то да се ради о пацијентима са дијабетесом, коју најчешће чини старија популација. Разлог пропуштања терапије као што је одсуствовање од куће такође може бити повезано са заборавношћу пошто је пацијент требало да се сети да понесе своје лекове са собом. Следећи разлог који је пријављен у свим истраживањима је био недостатак лека, што би такође могло бити повезано са заборавношћу, односно неуспех прикупљања или куповине лекова на време (Убавић и сар. 2019). Боља адхеренца ће побољшати квалитет живота пацијената, али и спречити нежељене догађаје који могу настати због непоштовања договорене терапијске шеме.

Општи упитници за процену здравствене писмености се не баве адекватно специфичним вештинама везаним за фармакотерапијску писменост, и постоји неколико специфичних упитника који се примењују за процену писмености пацијената у вези са лековима (*Tavousi* и сар. 2022). С тим у вези креиран је специфичан упитник за пацијенте са дијабетесом, *PTHL-DM* који процењује вештине везане за приступ, разумевање и коришћење информација о лековима, као и способност доношења одлука на основу разумевања информација. Дакле, укључује под-димензије које су предложили *Pantuzza* и сар. (2022). Посебно креиран *PTHL-DM* упитник је прилагођен специфичним потребама пацијената са хроничним болестима, односно дијабетичарима. Он се користи за процену перформанси, односно вештина у сва три домена здравствене писмености, и укључује лекове прописане на рецепт и оне који то нису. Процена и подршка довољним вештинама *PTHL* је приоритетна област у безбедности лекова у ситуацијама високог ризика, полифармацији и транзицији неге. Поузданост *PTHL-DM* је била веома добра за дванаест питања, једно питање је показало добру, и два питања скромну поузданост. Слични налази су уочени и у истраживању спроведеном у Србији на родитељима деце предшколског узраста (Убавић и сар. 2019). Такође, кроз *KP20*, *ICC* коефицијент и тест-ретест поузданости доказано је да је

конструисан *PTHL-DM* упитник поуздан и валидиран упитник за примену код ове популације пацијената.

Други циљ

Неке претходне студије које су процењивале нивое здравствене писмености мерене коришћењем различитих инструмената у истој популацији показале су да мали проценат пацијената има адекватну здравствену писменост, са пријављеном преваленцијом у распону од 15% до 40%. Многе од ових студија су спроведене у развијеним западним земљама (САД и УК) (*Haun* и сар. 2012; *Rothman* и сар. 2004). Међутим, било је ограничено објашњење уочених разлика у преваленцији и није било напора да се овај проблем сагледа глобално. Удео пацијената са неадекватном здравственом писмености у нашој студији био је од 33% до 37%, и био је сличан неким студијама спроведеним у САД (32,8%, 26,3%, 37,2%), Бразилу (26,7%) и Маршаловим Острвима (24%) (*Abdullah* и сар. 2019). Студија са највећом преваленцијом неадекватне здравствене писмености (82%) спроведена је 2012. године на Тајвану (*Chen* и сар. 2014), а најнижа преваленција неадекватне здравствене писмености (7,3%) је пријављена 2011. године у Швајцарској (*Franzen* и сар. 2014) међу пацијентима са дијабетесом. Утврђено је да постоји потреба да земље процењују ниво неадекватне здравствене писмености код пацијената са дијабетес мелитусом тип 2 користећи један стандардизовани упитник. Стандардизована метода мерења здравствене писмености би омогућила директно поређење резултата између земаља (*Sørensen* и сар. 2013).

Трећи циљ

Без обзира на коришћене упитнике, уочене су значајне разлике у здравственој писмености у односу на образовање. Пацијенти са дијабетес мелитусом тип 2 који имају завршено универзитетско образовање пријавили су значајно већи ниво здравствене писмености од оних са средњом школом и нижим нивоом образовања. Ово је у складу са резултатима *Heijmans* и сар. (2015), *Mor-Anavy* и сар. 2021, *Hussein* и сар. (2018), *Vandenbosch* и сар. (2018), *Berkman* и сар. (2011) и *Jeppesen* и сар. (2009), који су користили различите упитнике; и резултатима оних који су користили *FCCHL* за мерење здравствене писмености у овој популацији, *Nutbeam* и сар. (2017), *Al Sayah* и сар. (2015) и *Finbråten* и сар. (2018). Међутим, просечна старост узорка је била релативно висока, тако да разлике у вези са годинама можда нису биле евидентне. У истраживању које су спровели *Abdullah* и сар. (2019) у Малезији није било значајне повезаности између нивоа образовања и здравствене писмености. Већи узраст и ниже образовање су у директној корелацији са нижим капацитетом људи да доносе разумне одлуке у контексту свог свакодневног живота; њихова способност да заштите, одрже и повећају контролу над својом болешћу и здрављем је смањена. Лоше здравље и лошији здравствени исходи се стално виђају међу пацијентима са сложенијом потребом за негом; ови налази наглашавају потенцијалну улогу здравствене писмености у овом односу. За разлику од ранијих истраживања *Jeppesen* и сар. (2009) и *Finbråten* и сар. (2018), код нас је добијена повезаност између здравствене писмености и здравственог понашања (конзумација алкохола и навике пушења) са применом *FCCHL-SR12*

упитника и комбинованом применом *BRIEF-3* и *FCCHL-SR12* упитника. Препоруке о пушењу и конзумацији алкохола промовисане су међу особама са дијабетесом, и стога би информације о пушењу и ризику од алкохола могле бити лакше разумљиве без обзира на ниво здравствене писмености у поређењу са другим здравственим понашањима. Здравствена писменост би могла бити повезана са ризичним здравственим понашањем, укључујући пушење, конзумацију алкохола и употребу супстанци, што указује да би особе са нижом здравственом писмености могле бити подложније употреби различитих супстанци и/ или зависности (*Rolova* и сар. 2020).

Конзумација алкохола, пушење и недостатак физичке активности били су у директној корелацији са ниском фармакотерапијском писмености. Генерално, студије се слажу да здраве промене понашања и губитак тежине могу значајно спречити или смањити ризик од дијабетес мелитуса тип 2 (*Tabak* и сар. 2012). Самопроцена здравственог стања према литературним подацима такође представља други фактор који утиче на фармакотерапијску писменост (*Baron-Epel* и сар. 2007; *Cho* и сар. 2008). Извор здравствених информација је значајан предиктор ниске фармакотерапијске писмености, резултати истраживања су показали да постоји већа вероватноћа ниске фармакотерапијске писмености ако је информација добијена од лекара у поређењу са фармацеутима, док је највећа вероватноћа за ниску писменост уколико је извор информација интернет или остало. Нешто другачији налази добијени су у истраживању родитеља деце предшколског узраста, које је показало најмању вероватноћу неадекватне писмености уколико су информације добијене од лекара. Један од разлога зашто се процењује већа фармакотерапијска писменост код пацијената чији је главни извор информација фармацеут је тај што су фармацеути најприступачнији пружаоци здравствених услуга, они су кључни играчи у здрављу пацијената, не само у смислу скрининга, већ и у доживотном управљању болести.

Четврти циљ

Веза између адхеренце према терапији и контроле гликемије је анализирана у 42 студије, од којих је 30 испитало оралне антидијабетике или више група антидијабетика. Боља адхеренца код примене антидијабетика је генерално била повезана са побољшаном контролом гликемије. Значајно веће смањење у *HbA1c*, или нижи *HbA1c*, код адхерентних у односу на неадхерентне пацијенте је пријављен у већини истраживања (*Evans* и сар. 2022). Студије су такође приказале знатно већа вероватноћу да ће више адхерентних пацијената постићи специфичне вредности *HbA1c*, као што је смањење од ≥1,0% или смањење на <7%, од мање адхерентних пацијената. Једно истраживање пријавило је смањење *HbA1c* које није било статистички значајно код адхерентних испитаника (*Reynolds* и сар. 2016). Слични резултати су добијени у овом истраживању , *HbA1c* ≤7% код адхерентних пацијената (57,9%), наспрам неадхерентних (34,3%), с тим да разлика није била статистички значајна (p=0,401).

У истраживању није пронађена повезаност неадекватне здравствене писмености ни са једним од узрока неадхеренце према терапији. У студији *Fan* и сар. (2016) ограничена здравствена писменост била је повезана са повећаном ненамерном неадхеренцом, као што је заборављање или проблеми да се пацијенти сете да користе лекове. Међутим, није утврђено да је здравствена писменост повезана са намерном неадхеренцом, што укључује престанак узимања лекова када се пацијенти осећају боље или лошије. У истраживању *Bains* и *Egede* (2011) није пронађена веза

између здравствене писмености и адхеренце код пацијената са дијабетес мелитусом тип 2. *Thurston* и сар. (2015) су показали да ограничена здравствена писменост није повезана са свеукупном адхеренцом на терапију, већ је повезана са повећаном вероватноћом пацијената са дијабетесом да заборављају да узимају своје лекове. Међутим, та студија није направила разлику између ненамерне и намерне адхеренце према терапији. *Lindquist* и сар. (2012) су открили да је здравствена писменост повезана са повећаном ненамерном неадхеренцом на терапију и смањеном намерном неадхеренцом код старијих пацијената. *Fan* и сар. (2016) су приказали сличну повезаност са ненамерном неадхеренцом, али не и са намерним неадхеренцом код пацијената са дијабетес мелитсуом тип 2. Разлике између резултата претходних студија могу проистећи из разлика у испитиваним популацијама и различитим варијаблама укљученим у статистичке моделе.

Здравствени радници морају циљано пратити адхеренцу према терапији и јачати сарадњу и мотивацију пацијента да се придржавају прописаном режиму лечења. Нарочито је ово изражено код старијих особа са полифармацијом, где је неопходно што више поједноставити режим лечења (*Leppée* и сар. 2014).

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4. ОБЈАВЉЕНИ И САОПШТЕНИ РЕЗУЛТАТИ КОЈИ ЧИНЕ ДЕО ДИСЕРТАЦИЈЕ

Радови објављени у врхунским међународним часописима (М21):

Levic M, Bogavac-Stanojevic N, Ubavic S, Krajnovic D. Pharmacotherapy literacy level and predictors of low literacy among diabetes mellitus type 2 patients in Serbia. BMC Public Health. 2023;23(1):1822. https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-16639-y

Назив часописа: BMC Public Health

Категорија: Public, Environmental & Occupational Health (75/300)

Импакт фактор (2022) = 4,5; М21

Levic M, Bogavac-Stanojevic N, Krajnovic D. The Instruments Used to Assess Health Literacy and Pharmacotherapy Literacy of Diabetes Mellitus Type 2 Patients: A Scoping Review. Front Public Health. 2021;9:1424-1440. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8502961/

Назив часописа: Frontiers in Public Health

Категорија: Public, Environmental & Occupational Health (39/302)

Импакт фактор (2021) = 6,461; M21

Рад објављен у истакнутом међународном часопису (M22):

Levic M*, Bogavac-Stanojevic N* Krajnovic D*. Cross-Cultural Adaptation and Validation of the Functional, Communicative and Critical Health Literacy Instrument (FCCHL-SR) for Diabetic Patients in Serbia. Healthcare (Basel). 2022;10(9):1667. (*equal contribution). https://www.mdpi.com/2227-9032/10/9/1667

Назив часописа: Healthcare (Basel)

Категорија: Health Care Sciences & Services (57/106)

Импакт фактор (2022) = 2,8; M22

Саопштење са скупа међународног значаја штампано у изводу (M34):

1. Krajnovic D, **Levic M**, Ubavic S. "Pharmacotherapy literacy instruments – What do we know so far?" 10th International Pharmaceutical Conference, Kaunus, Lithuania. 15th November, 2019. Abrstract book:97.

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2. Krajnović D, **Lević M**,Ubavić S. Zdravstvena pismenost pacijenata i njen značaj kod savetovanja pacijenata sa hroničnim bolestima. 4. kongres farmaceuta Crne Gore sa međunarodnim učešćem, 11-14. maj 2023 Budva, Bečići, Crna Gora. Abstrakt book:32-33.
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5. ЗАКЉУЧАК - ОБРАЗЛОЖЕЊЕ НАУЧНОГ ДОПРИНОСА ДОКТОРСКЕ ДИСЕРТАЦИЈЕ

На основу детаљне анализе приложене докторске дисертације, чланови Комисије закључују да приказани резултати, дискусија и закључци представљају значајан допринос у области здравствене и фармакотерапијске писмености, с обзиром да тренутно постоје ограничени подаци о нивоу здравствене писмености код популације пацијената са дијабетес мелитусом тип 2 у Србији, ниво фармакотерапијске писмености није испитиван у свету и код нас за ову популацију, а доказано је да здравствена и фармакотерапијска писменост утичу на управљање терапијом, здравствене исходе и трошкове здравствене заштите.

Испитивања до сада су процењивала повезаност нивоа адхеренце са здравственом писмености, међутим нико се није бавио испитивањем везе између узрока неадхеренце према терапији са ниском здравственом и фармакотерапијском писмености, као и социо-демографским карактеристикама пацијената. Добијено је да су предиктори ниске здравствене писмености старије животно доба, мањи број деце, нижи ниво образовања као и већа конзумација алкохола. Вероватноћа ниског нивоа фармакотерапијске писмености повећана је међу пушачима, пацијентима који су своје здравље проценили као лоше, као и онима са ниским интересовањем за здравље. Пацијенти који су користили фармацеуте као извор информација имали су мање шансе да буду фармакотерапијски неписмени. Такође је уочена статистичка значајност између групе испитаника са ниском фармакотерапијском писмености код узрока примарне намерне неадхеренце да нису били код куће и да им се спавало када су требали да узму лек, оба из групе фактора који се односе на самог пацијента.

Сматра се да ће ови подаци помоћи у сагледавању неопходних мера за интервенције које би унапредиле писменост од стране лекара, фармацеута и укључиле процене здравствене и фармакотерапијске писмености у јавно-здравствене политике у Србији, самим и тим омогућиле бољу контролу болести ове изузетно распрострањене популације пацијената.

6. ПРОВЕРА ОРИГИНАЛНОСТИ ДОКТОРСКЕ ДИСЕРТАЦИЈЕ

На основу извештаја о провери оригиналности докторске дисертације Марије М. Левић, под насловом: **„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“,** коришћењем програма *iThenticate* регистровано **подударање текста износи 6%.** Овај степен подударности последица је претходно публикованих резултата истраживања докторанда, цитата, личних имена, општих места и података, што је у складу са чланом 9. Правилника.

На основу свега изнетог, а у складу са чланом 8. став 2. Правилника о поступку провере оригиналности докторских дисертација које се бране на Универзитету у Београду, **изјављујем да извештај указује на оригиналност докторске дисертације, те се прописани поступак припреме за њену одбрану може наставити.**

09.05.2024. год.

Ментор

_____

Др сц. Душанка Крајновић
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7. ПРЕДЛОГ КОМИСИЈЕ ЗА ОЦЕНУ ЗАВРШЕНЕ ДОКТОРСКЕ ДИСЕРТАЦИЈЕ

На основу изложеног, Комисија закључује да докторска дисертација кандидаткиње магистра фармације Марије М. Левић чија је израда одобрена на седници Већа научних области медицинских наука Универзитет у Београду (Одлука бр 61206-5l1/2-22 од 22.02.2022. године) задовољава критеријуме оригиналног научног дела. Кандидаткиња је успешно реализовала постављене циљеве истраживања, а резултати приказани у овој докторској дисертацији представљају оригинално и самостално научно дело са значајним научним доприносом у области социјалне фармације и истраживања фармацеутске праксе. Резултати докторске дисертације су публиковани у **два рада у врхунским међународним часописима (М21)** и у **једном раду у истакнутом међународном часопису (М22).**

Комисија у наведеном саставу позитивно оцењује докторску дисертацију магистра фармације **Марије М. Левић** под насловом: **„Предиктори ниске здравствене и фармакотерапијске писмености и њихова веза са узроцима неадхеренце према терапији код пацијената оболелих од дијабетес мелитуса тип 2“** и предлаже Наставно-научном већу Фармацеутског факултета, Универзитета у Београду да прихвати овај Извештај о израђеној докторској дисертацији и упути га Већу научних области медицинских наука ради добијања сагласности за јавну одбрану докторске дисертације.

10.05. 2024**.** **Комисија за оцену и одбрану докторске дисертације**

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Pharmacotherapy literacy level and predictors of low literacy among diabetes mellitus type 2 patients in Serbia

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Abstract

Background Pharmacotherapy literacy (PTHL) is a specific ability to safely access, appraise and understand the available information concerning medication and to calculate and act accordingly. The concept of PTHL is mostly unknown for the majority of diabetes mellitus type 2 (DMT2) patients in Serbia. With diabetes being one of the major public health problems in Serbia with a prevalence of 9.1%, this two-study research aims at constructing performance-based instrument and estimating the prevalence of PTHL levels and identification of predictors of low PTHL scores in patients with DMT2.

Methods Multistage study was performed to adapt the existing performance–based instrument (PTHL-SR) into specific questionnaire for DMT2 population (PTHL-DM instrument). PTHL levels were assessed through cross-sectional study categorising patients into groups of low, medium, and high PTHL levels. We considered 19 predictors for low PTHL scores, from sociodemographic characteristics, health behaviours and health characteristics, access to health-related information and empowerment-related indicators. Univariate and multivariate logistic regression analyses were used to determine independent predictors of low PTHL.

Results The final 15-item PTHL-DM instrument proved to have satisfactory reliability (KR20 = 0.475) and internal reliability [ICC for the whole instrument was 0.97 with 95% confidence intervals (0.95–0.99)]. Positive correlation (rho = 0.69) between PTHL-DM score (15 questions) and the total PTHL-SR score (14 questions) was also observed.

It was demonstrated that the majority of 350 patients had low PTHL (62%), and only 5% high PTHL level. Mean score on PTHL-DM was 7.8 ± 2.3. Probability of low PTHL increased among smokers, patients with low interest in health and those who estimated their health as bad. Patients who used pharmacists as sourse of information were less likely to be pharmacotherapy illiterate. Combined therapy with insulin and Oral Hypoglycemic Agents was associated with higher PTHL.

Conclusions Our data indicate that specific PTHL-DM tool is objective, valid, and reliable. It was found that low level of PTHL prevailed among DMT2 patients. Medication literacy is influenced by age, residence, education, and family status. Patients with better health literacy also reported better health behaviours. Different patient empowerment programs and approaches aimed at raising PTHL would be essential to improve self-management and control of this widespread chronic disease in Serbia.

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Keywords Literacy related to medicines, Patients, Diabetes mellitus type 2, Self-reported instruments, Self-management

Background

An adequate level of pharmacotherapy literacy (PTHL) is extremely important for chronic patients in order to properly use their prescribed therapy [1, 2], reduce the number of adverse events, improve medication adherence [3], and prevent hospitalisations [4].

These patients have to continuously implement different activities for proper management of their therapy. The concept of health literacy (HL) is of growing importance in public health and the healthcare system. Possession of appropriate knowledge and skills contributes to the prevention of diseases, improvement of health and quality of life. The concept in itself is insufficient for chronic patients who require certain knowledge about the use of medicines to control their disease. Therefore, a new term was required that would deal with literacy related to the use of medicines. In the relevant literature there are several names proposed, such as: "medication literacy" [5] "medical literacy" [3, 6], and "pharmacotherapy literacy" [7]. The most widely used definition of PTHL implies: "The individual's capacity to find, evaluate, calculate, and understand reliable information related to pharmacotherapy and pharmacy-related services that is needed to make appropriate medication-related decisions, regardless of the method of transmission and the content of the information (written, spoken information, image or symbol), and thereby reduced the risk of bad outcomes of pharmacotherapy" [8, 9]. This definition was modified by Pantuzza et al. (2022) by adding the term "assess" and "digital information" so that the latest definition reads: "The degree to which individuals can obtain, understand, communicate, calculate and evaluate patient-specific information about their medications to make informed medicin and health decisions, to use their medications safely and effectively, regardless of how the content is delivered (eg written, oral, digital and visual)". As pharmacotherapy literacy is derived from health literacy specifically targeting medication-related skills, Pentuzza et al., adopted the definitions of functional, communicative, and critical literacy known from Nutbeam [10], and the concept of numeracy proposed by Golbeck et al. (2005) [11]. Hence, the suggested conceptual model identified specific components for literacy in the context of medication use and in this way expands known HL's concepts capturing broad skills that influence medication use [12]. It encompasses dimensions of functional literacy, communicative literacy, critical literacy, and numeracy with its respective subdimensions (understand, access, communicate, evaluate, calculate) smedication-related information [12].

Patients who have a lower level of PTHL are more susceptible to medication addiction. Recognising such patients in everyday practice is difficult. For this purpose, a set of questions was developed in the form of a questionnaire—Recognition and treatment of patients with low pharmacotherapeutic awareness (RALPH). High health awareness is crucial for patients to be able to understand information and instructions related to their medical treatment. A significant number of patients do not have a sufficient level of health awareness and literacy. Such patients face difficulties in interpreting the information related to the prescribed medicine. The timely identification of such patients with potentially low pharmacological awareness, which we will call PTHL, is certainly important, given that those patients may be at increased risk of medication addiction. Previous research has shown that pharmaceutical staff primarily use their gut feeling or certain patient characteristics to identify patients with lower health literacy. The RALPH method presents a questionnaire as a practical tool for identifying those patients. The results showed that most patients with diabetes have sufficient knowledge about how often and when they should take their medicines, but also that they are more prone to encountering problems in more complex tasks such as interpreting warnings and precautions and critically analysing the information obtained about the medicine [4]. Identifying available and effective methods to improve PTHL among patients is one of 20 research priorities, highlighted in a study that used an inclusive, systematic, and replicated process to define medication safety research priorities [13]. In this regard, the World Health Organization (WHO) launched the third WHO Global Patient Safety Challenge, "Medication Without Harm", in 2017, which seeks to facilitate a series of strategic initiatives aimed at improving medication safety worldwide [14].

PTHL in people with diabetes mellitus type 2

DM is one of the chronic diseases that require high PHTL levels because patients self-regulate their dose of therapy on a daily basis.

It was found that despite advancedtherapy and the availability of different guidelines for clinical practice, only about 30% of patients with DM manage to achieve target glycemia and blood pressure values [15]. An

appropriate PTHL level will help with their awareness of therapy and health behaviour.

Patients with DM and low PTHL have different issues with understanding of instructions, different health advices and warnings. These patients also have poorer communication with healthcare professionals [16, 17]. For this reason, it is very important to assess their PTHL level and implement appropriate training in order to improve control over the disease itself. Numerous interventions in upgrading education have shown good results in patients with low PTHL and improved diabetes outcomes [18, 19].

Predictors associated with HL and PTHL

Sociodemographic factors, lifestyle and environment, may interfere an individual's skills and knowledge about PTHL. It was confirmed that education level, age, and income level can influence making the right health decisions [20–22].

Some research indicates that HL can help prevent health inequalities marginalised populations [21–25].

The objectives of the research are to adapt the existing performance-based instrument currently used in the Serbian language in relation to medicines, making it specific to DMT2 patients and to identify its validity and reliability before using it for the assessment of PTHL and identification of predictors of low PTHL.

Methods

Research studies

We conducted two-study research: first, we constructed the instrument (formatted and adapted the existing instrument [7] and gathered data for its psychometric properties) and then we applied it. As we needed a specific and performance-based instrument in the Serbian language to be able to assess PTHL in DMT2 patients, in the first study, we adapted pre-existing self-reported objective medication instrument in Serbian (PTHL-SR), [7, 9] to make it specific to the DMT2 population (PTHL-DM). A cross-sectional study design was adopted for the data collection, first for validation of the measuring instrument between January 2021 and June 2021 and then for the evaluation study during December 2021 and between March and May 2022.

The target population of this research for both studies were patients diagnosed with DMT2 at least six months before the start of the study, who knew the Serbian language, aged 18 and older and voluntarily agreed to participate with signed informed consent. The exclusion criteria were participants with medical backgrounds (e.g., doctors, study nurses, and those with blindness, dementia, or psychotic disorder). The data collection was carried out at one Community Healthcare Center in the municipality of Zvezdara and one Community pharmacy from the municipality of Vozdovac. Both municipalities are located in Belgrade, the capital of Serbia. Users of internal medicine services in Belgrade are mostly middle-aged or elderly. In 2020, the scope of work of internal medicine services in the Healthcare Center "Zvezdara" included 24,287 examinations, where the daily overload was slightly more than 19 examinations. This is almost 10% of all internal medicine examinations performed that year in all municipalities of Belgrade [26]. This is a typical primary healthcare institution for those patients, and it fully represented a demographically diverse population. The adequate age and gender distribution of the sample reflected the targeted population well and could be considered representative of elderly people of DMT2 in the country [27]. According to the 2022 census, Zvezdara has 171,278 inhabitants, of which 80,084 are men and 91,194 are women, or 10% of the population of Belgrade and approximately 3% of the population of Serbia. Zvezdara includes 4 municipalities, the largest that is urban area and 3 suburban areas [28].

In Vozdovac there are 169,695 inhabitants, or 9% of the population of Belgrade and approximately 2.5% of the population of Serbia. It contains 36 settlements, from urban, suburban, and rural areas. These two municipalities were chosen for recruitment, since the highest proportion of persons are registered as permanent community, and both rural and urban areas are covered. Patients from all parts of those municipalities were represented to reflect the geographical distribution in the target population [29].

Residents of Belgrade account for a fifth of those who died from diabetes in Serbia. They predominantly suffer from type 2 diabetes, from which in 2021, 1,728 people (87.7% of the total number of new cases) fell ill. Of the total number of DMT2 patients registred in Belgrade (81.257 on December 31,2021), one third belonged to the population of 65 and over. In our sample this age group was slightly over represented (39.3%). The prevalence of diabetes is higher in males, with the difference between the sexes being the least present in older citizens in Belgrade who are 65 years and over [26, 30]. In our sample woman were prevalent, but man dominated in that age group (43.6%). All these indicates that the sample reflected the elderly with DMT2 population in Belgrade well.

Instrument construction and data collection in the first study

In the first study, a multi-phase procedure was carried out (Fig. 1) for the formation of the measuring instrument including: (1) Literature review to adapt the existing version of the PTHL-SR by rephrasing the items and

adding some new ones to create the initial PTHL-DM, (2) an expert panel for face validity of the adopted version (initial PTHL-DM), (3) pre-testing of the initial version and (4) a study to collect validity evidence and formation of the final version.

1) A review of the PubMed database was performed in order to find literature that dealt with the examination of PTHL persons with DMT2 or the knowledge and understanding of information about medication and their use in this population. Key words for the literature search were: "pharmacotherapy literacy", "diabetes mellitus type 2", "information", "knowledge", and "medications". This process generated a list of potential items that could be included in the existing version of PTHL-SR. It contains 14 medication-specific questions, divided by domains based on Nutbeam's research [31, 32] distinguishing three types of HL: functional, interactive/communicative, and critical. The domains of initial PTHL contain three types of HL: 5 questions to assess knowledge about the use of medicines, 3 questions to assess the understanding of written and spoken information about the use of medicines, 5 questions to assess the numerical abilities required for adequate administration of correct doses of medicine and 1 question related to access to information about medicines. Secondly, the authors worked together to revise some of the existing questions of the PTHL-SR to be diabetes–specific and made an initial version of PTHL-DM. Based on the literature, the authors divided the questions according to the areas (domains) relevant to proper use of medications, [33, 34], as medication-related literacy includes skills not only for patients to have access to sufficient information but also sufficient reading, coding and self-management.

2) The content of the questionnaire (initial PTHL-DM) was defined using expert review [35–37]. The expert panel consisted of three professors from the Faculty of Pharmacy in Belgrade, two pharmacists working in practice experienced with pharmacy practice research, one endocrinologist, and one general practitioner. The team of experts were aimed with assessing the face validity and making informal assessments that yield open ended comments about the PTHL-DM items to be evaluated. They discussed the importance and relevance of each potential correction, adaptation or additional item and additionally discussed: (i) the question form and answer form, (ii) the suitability of the information in question, (iii) the clarity of the graphic drawings that accompanied certain questions and (iv) whether or not the question should be in the instrument. After expert panel, the adapted version of PTHL-DM was created for the pre-test phase.

3) Pre-testing was carried out by filling in the initial PTHL-DM instrument from 10 participants suffering from DMT2, who were not later included in the study. By pretesting the instrument, additional data were obtained on the clarity, transparency, and format of the adapted PTHL–DM instrument [38].

After adaptation, the initial version of PTHL–DM instrument was pre-tested on 10 interviewed persons to check whether the items were understandable and logical. The mean age of interviewed participants in the pre-test was 62.7 ± 12.4 years, ranging from 34 to 79 years of age, of which 60% were males. After the pretest, the results were discussed with the group of researchers. A version of the PTHL-DM instrument containing 15 questions divided into 4 PTHL groups based on their definition was agreed upon—questions about access to information (2 questions), understanding (3 questions), interpretation (4 questions) and use of information (6 questions).

The following is an explanation of each definition:

- Access to health information refers to the ability to search for, find and obtain information.
- Understanding means the ability to understand the information found.
- Interpretation describes the ability to reproduce, select and judge and evaluate found health information.
- The use of health information refers to the communication and use of information in order to make decisions that maintain or improve health.

Eleven out of 15 questions were medication specific with a variety of medication information represented (medication name, dosing information, treatment indication, precautions, time and prediction of therapeutic effect etc.). Hypothetical prescription labels were part of the instrument. Some of the questions included graphic presentations of a standardised measuring device for dosage of liquid medicines. There were also questions related to interpretation of the composition, nutritional values, and declaration. Two questions were related more to disease/general health literacy and were not medication specific. (Fig. 1).

4) For collecting validity evidence for the 15-items instrument, following the recommended ratio of at least 10 participants for each instrument item, the adequate sample size was 150, to which we added

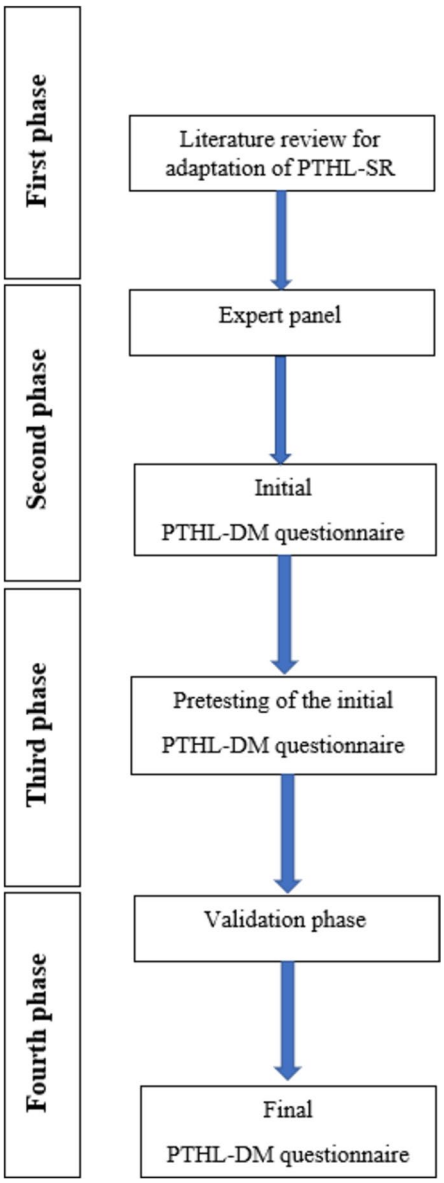

Fig. 1 Schematic diagram of the construction of the PTHL-DM questionnaire

10% to cover possible withdrawals [39]. Hence, we conducted a study on a convenient sample of 164 DMT2 patients. but 14 responders were excluded from the analysis due to not fulfilling 90% of the instrument.

Before this survey, we recruited five research assistants to help us with collecting data. To ensure that they were familiar with the purpose, process, and procedure of applying the instrument, we systematically trained three pharmacy graduates and two doctors as research assistants. The interviewers (researchers and assistants) explained the purpose and significance of the study to the participants and obtained written informed consent. Study participants were interviewed face-to-face for collection of sociodemographic data. The instrument applied in this validation study was self-administered in paper-and-pencil form. At any moment, at least one interviewer was present to provide all necessary explanation. Participants did not receive any payment for participation. All data was entered as anonymous into the database.

Sample and data collection for the second study

The required number of participants was calculated based on the population of DM patients in the Belgrade (80.241) area. The share of adult residents aged 20 to 64 in the total population in Belgrade in 2020 was 60.2%, and the share of the population aged 65 and over in the total population was 20% [26]. For calculation, we used estimated percentage of high PTHL from the literature, which was 72,83% [41, 42], and 95% confidence interval with an error of 5%. Based on these parameters, the required sample was at least 353. The required sample size of 353 was increased by 10% due to potential dropouts (accounting for the non-responder rate) during the study. A total of 385 DMT2 patients were approached, of which 90% agreed to participate. The final sample consisted of 350 DMT2 participants. The instrument for PTHL (PTHL-DM) was filled out voluntarily and anonymously by the participants after they had received the necessary and detailed information from the interviewers about the aim and the course of the research. Glycemic control was assessed by the most recent HbA1c value in the patient`s medical record at doctors` office, or from the laboratory record that patient brought along with them to their pharmacy visits. Sociodemographic characteristics of participants included age, gender, marital status, children, education level, employment and income. Health characteristics and health behaviors` information included HbA1c value, therapy, frequency of therapy application, exercise, alcohol and smoking were related to. Access to health-related information (a primary source of information), and empowerment-related indicators (perceived interest in one's health and perceived self-assessment of one's health in general) were recorded as well [43, 44]. Health literacy was assessed the same way like PTHL, using the validated multidimensional perception-based instrument—FCCHL-SR12 instrument [45].

Data analysis

To assess the inter-rater (test – retest) reliability or consistency among the observational ratings, we calculated Kappa coefficient for the dichotomous data. The Kappa coefficient value was defined by Altman [46]. Interclass correlation coefficient (ICC), kurtosis and skewness

were calculated for the items in each domain and the whole instrument. Also, the relationship for the domains between these PTHL-SR and PTHL-DM was examined by Spearman correlation.

Data normality for continuous variables was tested by the Kolmogorov–Smirnov test. Non-normal continuous variables are described by median and inter-quartile range, while normally distributed variables are presented by mean and standard deviation.

Categorical variables are spresented by absolute and relative frequencies and the difference between groups of categorical variables was examined by the chi squared ($\chi 2$) test of independence.

The responses on the PTHL-DM instrument were dichotomised into correct response (given a value of 1) and incorrect response / the patients didn't know (given a value of 0). The values were then summed up and the total PTHL-DM scores were obtained. Additionally, for each patient, the percentage of correct answers was calculated. As described previously [9] respondents were categorised according to their levels of PTHL-DM into those with a low level of PTHL (up to 8 correct answers (<60%)); medium level of PTHL (between 9 and 11 correct answers (60–80%)); and high level PTHL-DM (between 12 and 15 correct answers (>80%)). Access to information, understanding, interpretation and use of information showed skewed distributions and differences between the PTHL-DM levels groups were compared by the Kruskal Wallis test. Age showed normal distribution and it was compared by ANOVA.

Sociodemographic characteristics, healthcharacteristics and health behaviors, access to health-related information, and empowerment-related indicators were used as predictors of low PHTL level in univariate logistic regression analyses. Multivariate logistic regression analyses was used to determine independent predictors of low PTHL. Overall, *p* values less than 0.05 were considered significant.

All analyses were performed using IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY, USA: IBM Corp. It was conducted by Jamovi Statistical Software (Idaho State University).

We conducted this study following the recommendations of the STROBE checklist [47].

Results

First study: Validation phase

Firstly, all questions from the PTHL-DM were analysed for the KR calculation. The KR20 score was 0.475.

Mean scores for PTHL-DM domains and total PTHL-DM and their reliability parameters are presented in Table 1. Skewness for the domain Access to information showed outliers in a distribution, other domains and total PTHL showed slight asymmetry and the majority had a negative coefficient, which pulls the mean value towards a lower value. Apart from the domain Access to information, kurtosis for others was negative and indicated the small outliers in a distribution.

To determine the instrument's consistency in the repeatability dimension, the ICC for the whole instrument was calculated to be 0.97 with 95% confidence intervals (0.95–0.99). Kappa coefficient was 1.00 for questions number 2, 3, 4, 5, 7 and 14, it is in the range 0.94–0.99 for questions number 1, 6, 8, 9, 11 and 15, and there are questions with lower ICC (number 10 = -0.47, 12 = 0.58 and 13 = 0.83).

Correlation

The relationship between the total PTHL-DM score (15 questions) and the total PTHL-SR score (14 questions) was good (rho = 0.69). A good correlation is for domain understanding (0.74), while for domain knowledge/interpretation and use of information is somewhat weaker (0.43, 0.50, respectively).

Table 1 Scores and reliability parameters for PTHL-DM domains and total PTHL-DM

	Domain				
	Understanding	**Access to information**	**Interpretation**	**The use of information**	**PTHL-DM**
N of questions	3	2	4	6	15
Xsr ± SD	1.2 ± 0.8	1.7 ± 0.5	1.8 ± 0.9	3.5 ± 1.6	8.2 ± 2.3
Skewness	0,2	-1.3	-0.2	-0.3	-0.1
Kurtosis	-0.7	0.8	-0.5	-0.3	-0.8
Correct answers (Min—Max)	0–3	0–2	0–4	0–6	3–13
ICC (95% CI)	0.98 (0.96–0.99)	0.58 (0.11–0.80)	0.93 (0.83–0.97)	0.95 (0.89–0.98)	0.97 (0.95–0.99)

Second study: Measurement of pharmacotherapy literacy

In total, 350 patients participated in the second study. The average age of participants was 62 ± 10.5 years ranging from 31 to 82 years of age. The percentage of participants with 65 age and older was 40% ($n=139$). The majority of respondents were female (55.4%), married (53.8%), and individuals with higher education (60.6%). The prevalence of males and females aged 65 and older was similar (43.6% in males and 36.6% in females, $p=0.184$). According to therapy regimen, the majority of respondents (76%) were on diet and Oral Hypoglycemic Agents (OHAs).

Percentage of correct answers in investigated PHTL-DM instrument

The distribution of correct answers (%) for the final PTHL-DM instrument in DMT2 patients is shown in Fig. 2. More than 80% recognised the medicine, while less than 30% of respondents were aware of side effects and precautions and interpretation of dispensing label instructions for over-the-counter medicines.

For most questions, the difference between percentage of correct and wrong answers was statistically significant, except for questions 4, 7 and 15. Analysis of questions that reflect the extent of understanding domain in PTHL-DM showed that 21% of patients did not give the correct answer, 50% of participants gave one correct answer out of a total of 3. Regarding the domain Access to information, only 6% of participants had 1 correct answer, and 70% had both answers correct. The domain Interpretation showed 9% of participants had all incorrect answers, and 43% of them in the largest group had 2 correct answers, out of 4. The domain Use of information presented the least group of participants with all incorrect answers (3%) and the highest percentage of patients had 4 correct answers (28%), out of a total of 6.

Analysis of PTHL domains

The mean PTHL-DM total score was 7.8 ± 2.3, and scores for understanding, access to information, interpretation and use of information domains were 1.2, 1.6, 1.8 and 3.2, respectively. The range of correct answers for total PTHL-DM scores was from 3 to 13.

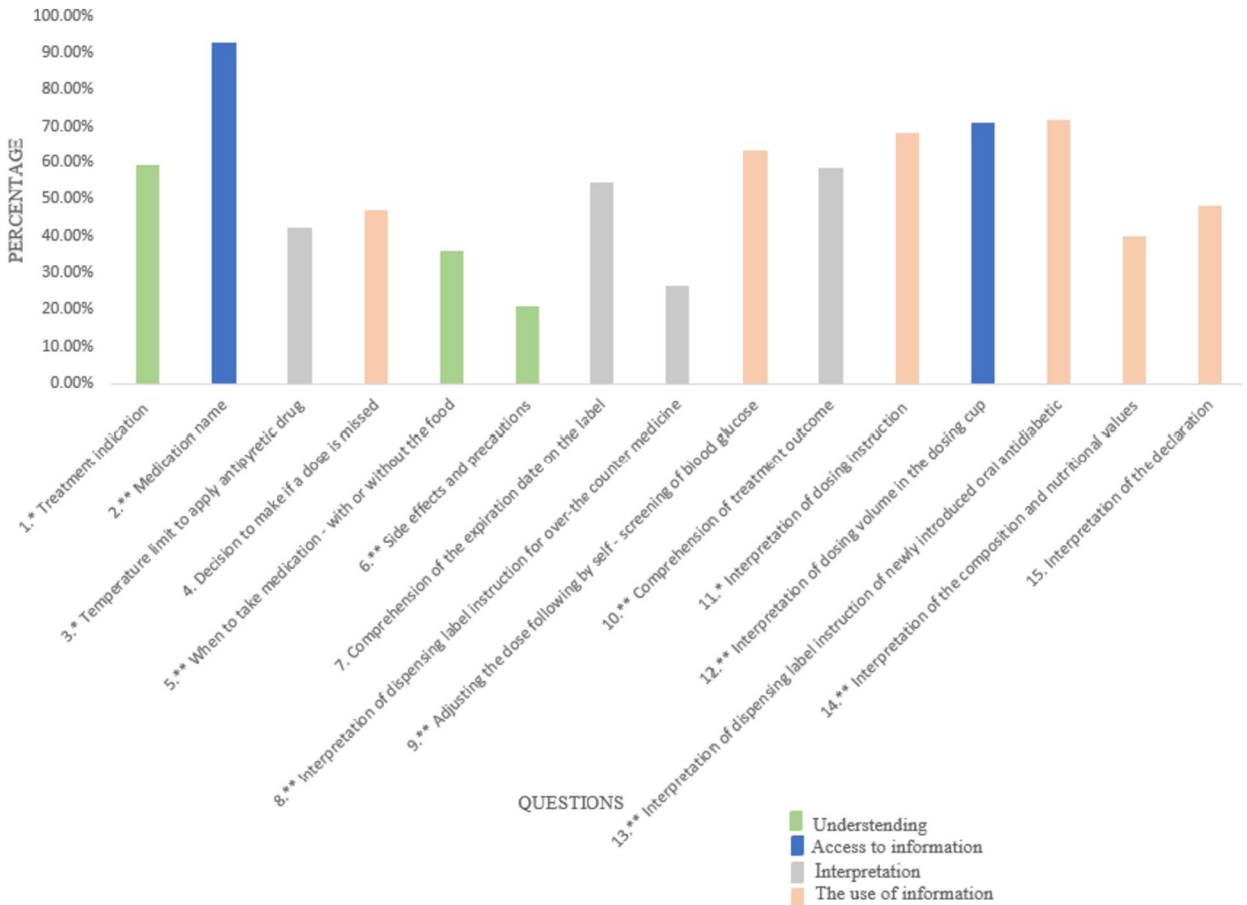

Fig. 2 Distribution of correct answers (%) by questions in the final PTHL-DM instrument ($n=350$)

Table 2 Sociodemographic characteristics and health behaviours of DMT2 patients stratified by PTHL level

	Characteristics	Total (*N* = 350)	PTHL level			χ2/p*
			Low (*N* = 216)	Medium (*N* = 117)	High (*N* = 17)	
Gender, N (%)	Male	156 (44.6)	97 (62.2)	54 (34.6)	5 (3.2)	1.71/0.425
	Female	194 (55.4)	119 (61.3)	63 (32.5)	12 (6.2)	
Marital status, N (%)	Single	158 (45.1)	97 (61.4)	53 (33.6)	8 (5)	0.03/0.984
	Married/Common-law	188 (53.8)	117 (62.2)	62 (33.0)	9 (4.8)	
Children, N (%)	No	91 (26.0)	29 (31.9)	51 (56.0)	11 (12.1)	4.47/**0.001**
	One child	91 (26.0)	20 (22.0)	54 (59.3)	17 (18.7)	
	Two or more children	168 (48.0)	80 (47.6)	64 (38.1)	24 (14.3)	
Level of education, N (%)	Secondary school or less	138 (39.4)	96 (69.6)	41 (29.7)	1 (0.7)	11.23/**0.004**
	College/university/post-graduate	212 (60.6)	120 (56.6)	76 (35.8)	16 (7.5)	
Employment, N (%)	Employed	219 (62.6)	131 (59.8)	76 (34.7)	12 (5.5)	1.09/0.579
	Unemployed or Pensioner	131 (37.4)	85 (64.9)	41 (31.3)	5 (3.8)	
Monthly income per family member, N (%)	< 40,000 RSD	88 (25.1)	64 (72.7)	23 (26.1)	1 (1.1)	8.03/0.091
	40,000–60,000 RSD[a]	228 (65.1)	134 (58.8)	80 (35.1)	14 (6.1)	
	≥ 60,000 RSD	34 (9.8)	18 (52.9)	14 (41.2)	2 (5.9)	
HL[b]	Inadequate HL	116 (33.3)	72 (62.1)	40 (34.5)	4 (3.4)	9.19/0.057
	Marginal HL	222 (63.3)	141 (63.5)	70 (31.5)	11 (5)	
	Adequate HL	12 (3.4)	3 (25)	7 (58.3)	2 (16.7)	
Active exercise, N (%)	Never	57 (16.3)	42 (73.7)	14 (24.6)	1 (1.8)	12.66/**0.049**
	Less than once a week	135 (38.6)	79 (58.5)	50 (37)	6 (4.4)	
	1–2 times a week	118 (33.7)	78 (66.1)	34 (28.8)	6 (5.1)	
	3 or more times a week	40 (11.4)	17 (42.5)	19 (47.5)	4 (10)	
Smoking, N(%)	Smoker	178 (50.9)	125 (70.2)	48 (27)	5 (2.8)	11.90/**0.00**3
	Non-smoker	172 (49.1)	91 (52.9)	69 (40.1)	12 (7)	
Alcohol intake, N (%)	Never	156 (44.6)	84 (53.8)	59 (37.8)	13 (8.3)	12.57/**0.01**4
	Once a month	121 (34.5)	82 (67.8)	35 (28.9)	4 (3.3)	
	2 or more times a month	73 (20.9)	50 (68.5)	23 (31.5)	0 (0)	

Abbreviation PTHL, Pharmacotherapy literacy, *HL* Health literacy

* Bold *p* values denote statistical significance

[a] 1RSD = 0.0085 EU

[b] Assessed with Serbian version of the Functional, Communicative and Critical Health Literacy Scale with 12 questions (FCCHL-SR12)

Analysis of levels of PTHL

When sociodemographic characteristics and low, medium and high levels of PTHL were analysed (Table 2), the results showed only 5% ($n = 17$) patients had high level of PTHL, 33.4% ($n = 117$) had medium and the rest were seen to have low PTHL level (62%, $n = 216$).

Higher ages are connected to low PTHL ($p = 0.038$). There was no statistical significance between PTHL level and HL score ($p = 0.999$), nor with years having diabetes ($p = 0.249$). The patients with one child were more prevalent in the group with high PHTL than those without children or with two and more children ($p = 0.001$). Patients with a low level of education (completed secondary school or less) were more prevalent in the group with low PHTL than their counterparts with higher education ($p = 0.004$).

With regards of HbA1c value, no statistical significance was found with PTHL level ($\chi2 = 3.03$, $p = 0.220$).

Treatment regimen for DMT2 showed that the highest percentage of highly literate patients is in the group receiving insulin and oral medication (12%) in comparison with patients on oral medication, insulin only or diet (3.1%, 0% and 0%, respectively). Significant statistical difference was found with respect to treatment regimen and PTHL level ($\chi2 = 19.63$, $p = 0.003$). A lower adequate literacy rate (low PTHL level) was observed for patients who take oral medications, then for those taking oral medication and insulin, diet and insulin only (65.3%, 54.7%, 50.0% and 22.2%, respectively).

Patients who have administrated a medication three or more times a day proved to have higher PTHL level

($\chi 2 = 6.78$, $p = 0.034$), than those taking the medicine once/twice a day.

The association of patients' access to health-related information and empowerment-related indicators with PTHL level is shown in Table 3. The results showed that low PTHL was least prevalent if the information was obtained from a pharmacist, in comparison to a doctor, internet or other sources ($p < 0.001$). The patients who are very interested in their health indicated higher PTHL ($p < 0.001$), as well as those who estimated their health status as good ($p < 0.001$).

Analysis of predictors for low PTHL

Univariate and multivariate predictor models

Sociodemographic characteristics of participants (gender, marital status, children, education, employment, income), therapy, frequency of administration, health behaviors (exercise, alcohol intake, smoking), access to health-related information, and empowerment-related indicators (interest in health and self-estimation of health status) were used as predictors of low PTHL. Unadjusted odds ratios (OR) and 95% confidence intervals (CI) for factors associated with patients' low PTHL were presented in Table 4. Predictors of low PTHL were higher age, lower education, lower income per family member, diet and OHAs used as a therapy, no active exercise, smoking status, alcohol intake, other sources of health information (information which were not received from doctors and pharmacists), little interest in health and bad estimation of health status.

Additionally, all significant predictors were included in multivariate analysis to assess independent predictors of low PTHL. Smoking was a significant independent predictor of low PTHL level. Little interest in health and assessment of health as bad were associated with a higher probability of low PTHL. The source of health information was also an independent predictor—a lower probability for low PTHL is seen if advice is received from a pharmacist compared to a doctor.

Discussion

The concept of PTHL is mostly unknown for the majority of Serbian population. To the best of our knowledge, this is the first research to investigate levels of PTHL among the DMT2 patients in Serbia. Measuring PTHL for chronic non-communicable diseases, especially DM, is important but it is also important to use a condition (disease or content) specific instrument [48]. We adapted the existing self-administered, performance-based instrument and proved that the new one is specific for assessing DMT2 patients' medication literacy with satisfactory psychometric characteristics. The correlation between the initial questionnaire (PTHL-SR) and the adopted questionnaire (PTHL-DM) was relatively good. Also, the domains of these questionnaires were examined, with the best correlation with domain of understanding. Very good reliability was shown for 12 questions, one question showed good and two questions modest reliability. Similar findings were seen in the research conducted in Serbia [7]. Also, the demonstrated reliability and internal reliability through KR20, ICC coefficient and test–retest reliability test proved that the constructed PTHL-DM questionnaire is a reliable and validated instrument. Furthermore, we found that low level of PTHL was highly prevalent in DMT2 patients and identified that smoking habit, who are smokers, low interest in owns health and self/estimation of owns health as bad could individually predict low PTHL.

Table 3 Access to empowerment-related indicators of the DMT2 patients stratified by PTHL level

	Characteristics	Total* (*N* = 350)	PTHL level			χ2/p*
			Low* (*N* = 216)	Medium* (*N* = 117)	High* (*N* = 17)	
Source of health information	Doctor	204 (58.3)	122 (59.8)	69 (33.8)	13 (6.4)	26.23/ **< 0.001**
	Pharmacists	47 (13.4)	17 (36.2)	27 (57.4)	3 (6.4)	
	Internet	15 (4.3)	11 (73.3)	4 (26.7)	0 (0)	
	Other	84 (24.0)	66 (78.6)	17 (20.2)	1 (1.2)	
Interest in health	Not interested/Little	142 (40.6)	98 (69)	44 (31)	0 (0)	26.56/ **< 0.001**
	Medium	172 (49.1)	102 (59.3)	60 (34.9)	10 (5.8)	
	Much or very interested	36 (10.3)	16 (44.4)	13 (36.1)	7 (19.4)	
Self-estimation of health status	Bad	99 (28.3)	57 (57.6)	41 (41.4)	1 (1)	20.57/ **< 0.001**
	Good	201 (57.4)	117 (58.2)	68 (33.8)	16 (8.0)	
	Very good	50 (14.3)	42 (84)	8 (16)	0 (0)	

Abbreviation PTHL Pharmacotherapy literacy

* Bold *p* values denote statistical significance

Table 4 Sociodemographic characteristics as predictors for low PTHL

Univariate analyses	**OR**	**95% CI**	***p* value**
Age[a]	1.035	1.014–1.058	0.001
Education			
(College/university/post-graduate)	0.755	0.602–0.947	0.015
Monthly income per family member[a]	0.619	0.420–0.912	0.015
Therapy for DMT2 (Insulin/Insulin and OHA)	0.564	0.343–0.926	0.024
Active excercise[a]	0.770	0.603–0.984	0.037
Smoking (Non smoker)	0.770	0.603–0.984	0.037
Alcohol intake[a]	1.429	1.072–1.906	0.037
Source of health information[a]			
Pharmacists	0.381	0.197–0.735	0.004
Internet	1.848	0.569–6.004	0.307
Other	2.464	1.364–4.453	0.003
Interest in health[a]	0.763	0.625–0.931	0.008
Self-estimation of health status[a]	1.236	1.007–1.518	0.043
Multivariate analyses	**OR**	**95% CI**	***p* value**
Smoking (Non smoker)	0.784	0.616–0.997	0.048
Interest in health[a]	0.439	0.255–0.757	0.004
Source of health information[a]			
Pharmacists	0.301	0.151–0.601	0.001
Internet	0.760	0.258–2.242	0.619
Other	1.471	0.862–2.510	0.157
Self-estimation of health status[a]	0.367	0.156–0.863	0.021

[a] Age – continuous variable, Monthly income per family member – ordered variable (< 40,000 RSD, 40,000–60,000 RSD, > 60,000 RSD 1 to 3), Active exercise – ordered variable (never, less than once a week, 1–2 times a week, 3 and more times a week were coded from 1 to 4), Smoking – ordered variable (smoker and non-smoker were ordered from 1–3), Alcohol intake – ordered variable (never, once a month, 2 or more times a month were ordered from 1–3), Source of health information – information received from doctors represented reference group, information received from Pharmacists, Internet and Other are coded 1,2 and 3 respectively, Interest in health – ordered variable (Not interested/Little, Medium and Much and very interested were ordered from 1–4), Self-estimation of health status (Bad, Good and very good were ordered from 1–3). Other Multivariate analyses were performed with significant predictors from univariate analyses

Diabetes prevalence (% of population ages 20 to 79) in Serbia was reported at 9.1% for 2021 [27, 30]. Diabetes prevalence grows with age, and it is estimated that almost a half of diabetic patients are over 65 years of age. In our sample patients over 65 years were represented with 40%. At the same time, the process of demographic ageing of the Serbian population manifests itself as a share of over 65 years of age is 21.3% [29]. Although diabetes is a major non-communicable and chronic condition that causes a significant degree of mortality and morbidity, to the best of our knowledge, no data is available for Serbia according to its prevalence by gender or levels of education. Some date is available regionaly, and by using data provided for the city of Belgrade we estimated the representativeness of study sample for the population of the elderly with DMT2 in Belgrade [28, 30].

Our foundings indicate the prevalence of patients with low PTHL level (62%).This was not in line with the research from Krajnovic et al., in Serbia [49], on the parents of pre-school children in which it was found that every tenth parent (10%) from rural areas and every fourth parent (25%) from urban areas had the highest PTHL level. Contrary to that, around half (51%) and one third (28%) of parents in rural and urban areas, respectively, had low PTHL levels. Having an elderly population perform the calculation with the mean-age of 62.5 years, who may have trouble reading and interpreting the questions, could offer an explanation for this. In the research conducted by Tefera et al. in Ethiopia [50], 17.3%, 26.3%, and 56.5% had low, medium, and high diabetic-related HL. This might be attributable to the variability of HL tools used, since the other tool measured informational, numeracy, and communicative HL relevant to diabetes. But also, the sociocultural and geographical variation might explain further differences.

According to the results, 21% of patients didn't give any correct answer on the questions for understanding –most of them could not correctly explain the warning about exposure to the sun during therapy. Access to information was better, with 70% of patients having both correct answers. Interpretation/knowledge showed good results, with only 9% of patients having no correct answers, The questions on showing the target glycemic range and expiration date were correctly answered by 43% of patients. The use of information was with expected distribution, and questions related to the calculation of dose were correctly answered by most of the patients. In the research with Diabetes Numeracy test (DNT-15) the results showed that the problems faced by patients with DM include proper calculation of insulin dosage based on current blood glucose levels and carbohydrate intake [51]. These findings were not in line with our findings, but this difference may be due to several factors. Firstly, in Serbia there are some diabetic guidelines [52]. Secondly, different social and environmental factors can cause anxiety among the participants and increase the number of errors performed during the evaluation [53].

High PTHL level and proper medication adherence can contribute to achieving good glycemic control and preventing different complications among DMT2 patients [54].

Furthermore, 19 factors are investigated that can impact the level of PTHL in DMT2 patients. Association between PTHL and key factors from sociodemographic characteristics (ages, level of education, number of children),, health-related information (treatment regimen and frequency of drug administration), health behavior

(alcohol intake, smoking and active exercise) and from empowerment-related indicators (source of health information, self-estimation of health and interest in health) was significant.

In this study, higher diabetic PTHL level is seen in males which is similar to finding in Tanzania [55] and Ethiopia [50]. However, no gender difference was found in these studies in achieving the targeted glycemic level. On the contrary, the researchers conducted in Japan [56] and Palestine [54] claimed that differences in gender can't be explained by different body composition and that further investigation to examine efficacy/treatment response with regard to gender is needed.

Many studies in the past have shown that age and education were important factors associated with mediation level. Significant increase in medication literacy level was observed by aging and when academic level of the participants increased [4, 6, 8, 9, 12, 33]. We found that older patients have higher probability of low PTHL. Aging implies a higher prevalence of chronic pathologies and therefore an increase in medication but also it influences the ablility not only to have sufficient information, but to interpretate and to calculate doses. Also, less educated DMT 2 patients and with lowest monthly income had a higher likelihood of low PTHL. Our results are supported by studies conducted in Ethiopia and China [50, 57] where higher education attainment and higher household income were significantly associated with adequate literacy. A significantly low diabetic HL was also reported in illiterate patients than those who have a higher level of education in United Arab Emirates (UAE) [58] and Bangladesh [59].

In our study's analysis, we found that patients who took medication three or more times a day, and those on insulin and OMAs proved to have higher PTHL level, which was expected as these patients have been exposed to a longer period of diabetes` education from the time of diagnosis. A similar finding was observed in the 2020 study conducted in the US [60]. A study by Singh et al. in India stated that patients receiving insulin therapy a significantly lesser score for interpreting prescription instructions when compared with those receiving only oral antidiabetics [61].

Alcohol intake, smoking and lack of physical activity were in direct correlation with low PTHL. In general, studies confirmed that changes in health behavior and weight loss can significantly reduce the risk of DMT2 [62].

Self-assessment of health status also represents another factor that affects PTHL [63–65]. The source of health information is a significant predictor of low PTHL, the research results showed that a probability of low PTHL decreses if the information is obtained from a pharmacist compared to a doctor, while the higher likelihood of low PTHL arises if the information is obtained from the internet or other source compared to a doctor.Slightly different findings were obtained in the research involvingparents of pre-school children, which showed the lowest probability of inadequate literacy when parents received information from doctors. One of the reasons why higher PTHL level is estimated in patients whose main source of information is a pharmacist is that pharmacists are one of the most accessible healthcare professionals. Pharmacists can counsel on monitoring glucose level, an appropriate diet and exercise routine and define the most appropriate hypoglycemic strategy for a certain patient [66]. Althogh DMT2 patients with one child were more prevalent in group with high PHTL than those without children or with two and more children ($\chi 2 = 4.47$, $p = 0.001$),we did not prove that number of children was a predictor of low PTHL level. Previous studies did not fully recognize this factor as important to investigate. We consider this factor important to include in our analysis as the safety of children is at risk due to parents' medication illiterateness.

The DMT2 patients with low interest in health, and those who estimated their health as bad, had higher probability for low PTHL. This aligned with research findings involving parents of pre-school children conducted in Serbia [67] and other research [68], that showed those patients who rated their health as only fair or poor are twice as likely to have inadequate HL compared to those who rate their health as either good or excellent.

Limitations

The scientific study ended up with some limitations, that are helpful for future investigations. The sample of this study used a convenient sample based on DMT2 patients selected from targeted healthcare institutions. Therefore, the study findings are limited to this sample, which could limit the generalisation of the results. Although diabetes is a major non-communicable and chronic condition that causes a significant degree of mortality and morbidity, to the best of our knowledge, no data on its prevalence by gender or levels of education is available in Serbia. Hence, our findings might not be generalized to overall Serbian DMT2 patients' population, we could prove some resemblance with the general population of Serbia. According to the Institute of Public Health of Serbia number of newly diagnosed cases of DMT2 in a Serbian population (0–75 + years) is higher in woman 52.3% [27]. There are more women than men (51.4% vs. 48.6%) in Serbia according to the Census in 2022 [28, 29]. In our sample woman are prevalent as well (55%) but this is not significant. The level of education in our sample was higher than that of the general Serb population; According to the 2022 census in Serbia, 16.4% of the population

has college, higher and university education, and 53.1% secondary education.

Another limitation involved in this research survey reported the difficulty in instrument answering, since it is quite lengthy. The diabetes illiterate participants may encounter problems filling in the forms. The comprehensiveness of the research results can be augmented by further investigations across specific geographic regions and in various cultures.

Conclusions

Among primary care patients with DMT2, low PTHL is independently associated with patients who are smokers, those with low interest in their health and patients who estimated their health as bad. Also, it is shown that patients who are on diet, OHAs or insulin only have higher probability for low PTHL than those on insulin and OHAs.

The current study revealed only the average number of diabetic populations have a medium PTHL level. Higher PTHL was reported in those patients who have one child, patients with the highest education, non-smokers, those who never consume alcohol and exercise 3 or more times a week. These patients are more likely to be highly literate with medications. Also, in Serbia a high percentage of DMT2 patients were found to have low PTHL.

Different patient empowerment programs and approaches aimed at raising PTHL would be essential in improving self-management and control of this widespread disease. Future research on a larger population in Serbia is necessary to draw conclusions about the levels of PTHL and their relationship with medication adherence and glycemic control.

Abbreviations

DMT2	Diabetes mellitus type 2
HL	Health literacy
PTHL	Pharmacotherapy literacy
OHA	Oral Hypoglycemic Agents
WHO	World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-023-16639-y.

Additional file 1. STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

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Authors' contributions

Conceptualization, D.K., and M.L.; methodology, D.K., and N.B.-S.; formal analysis, N.B.-S.; investigation, M.L.; resources, D.K.; data curation, M.L, and S.U..; writing—original draft preparation, M.L.; writing—review and editing, M.L., D.K., S.U., and N.B.-S. All authors have read and agreed to the published version of the manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and International Ethical Guidelines for Health-related Research Involving Humans, and approved by the Ethics Committee of the Health center "Zvezdara" (protocol code 4353/1, date of approval 29 December 2020) and Ethich Committee of the Community pharmacy "Filly farm " (date of approval 10 February 2022). Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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The Instruments Used to Assess Health Literacy and Pharmacotherapy Literacy of Diabetes Mellitus Type 2 Patients: A Scoping Review

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Background: Patients with chronic diseases, like diabetes need to continuously perform tasks associated with self-management especially with medications they use. It is shown that the patients with diabetes with limited HL and PTHL cannot read medication labels correctly, may misuse their medications, spend much more on therapy and generally have difficulties in understanding printed care instructions and perceiving health advice and warnings. There has been an increasing demand for valid and reliable instruments for HL and PTHL assessment in this population. This review aims to search and critically discuss instruments used to assess HL and PTHL in people with type 2 diabetes and propose their use in different settings.

Methods: Authors conducted a comprehensive, electronic search of original studies using a structured approach of the Scopus and PubMed databases, during November and the first 2 weeks of December 2020 to find relevant papers. The review was conducted in accordance with the Cochrane guidelines and the reporting was based on the PRISMA-ScR. The comparison of instruments was made by utilizing a comparison model related to their structure, measurement scope, range, psychometric properties, validation, strengths, and limitations.

Results: The final number of included studies was 24, extracting the following identified instruments: Korean Functional Test HL, NVS, FCCHL, HLS-EU-47, TOFLHA, S-TOFHLA, REALM-R, 3-brief SQ, REALM, HLQ and DNT-15. In all, FCCHL and 3-brief SQ are shown with the broadest measurement scopes. They are quick, easy, and inexpensive for administration. FCCHL can be considered the most useful and comprehensive instrument to screen for inadequate HL. The limitation is that the English version is not validated. Three-brief SQ has many advantages in comparison to other instruments, including that it is less likely to cause anxiety and shame. These instruments can be considered the best for measuring functional HL in patients with diabetes mellitus type 2 and other chronic diseases. PTHL instruments (REALM and DNT-15) did not find the best application in this population.

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Conclusions: The future research should be directed in validation of the FCCHL in English and establishing of the structural validity of this questionnaire. Developing a specific PTHL questionnaire for this population will be of great help in management of their disease.

Keywords: health literacy, medication literacy, measurement tool, assessment, patient, chronic disease, healthcare system

INTRODUCTION

The main goal of today's healthcare system is to promote and maintain good health and at the same time enable people to take care of their health. People are also expected to be more responsible for their health and participate more in decision-making related to their health (1–3). When we talk about responsibility for our health, we must consider different assumptions. Efforts should be focused on a person's ability to cope and take responsibility for their health (3). The Patients' Rights Act from 1999 states that the manner of participation in healthcare decisions should be adapted to each person's ability to give and receive health information. These abilities are related to health literacy (HL) (4).

To understand and use health information to make health decisions, adequate HL is needed (4). In a report by the World Health Organization (WHO), HL is one of the most important determinants of health. HL can be considered necessary to control and monitor one's health (5). Several studies have shown that most people have limited HL (6–12). Also, people with low HL are more likely to be with poorer health, more prone to complications, and have a higher mortality rate than people with high HL (5).

Healthcare professionals should consider that individuals possess different levels of HL. Therefore, knowledge about HL of people is necessary to adapt better health professionals' communication with different target groups, which would make the information more beneficial for the individual by enabling them to participate in health decisions and take responsibility for their health (13).

Optimizing health communication can prevent misunderstandings and other complications, thus the quality of care and patient safety would be improved (13). In order to meet expectations such as increased participation and responsibility for one's health, it is necessary to consider HL in individuals and the general population. The purpose of today's public health policy is to create conditions for educating people to be able to take control of their health and control it (3). Therefore, measuring HL in different populations would provide essential knowledge that would be used to improve health communication, and thus the ability of individuals to control their health. However, the validity and reliability of individual HL instruments have not been adequately established (14) and only a few HL instruments were validated using modern test theory, such as Rasch modeling (15, 16).

Health Literacy

Adequate health literacy is crucial for patients to make optimal choices for their health and medications management. Additionally, successful health communication presupposes certain levels of competence of both the healthcare professional and the patients and is adapted to the HL of the individuals (5).

"HL" as a recognized term came into use around 1974, but only became a [Medical Subject Headings (MeSH)] term in MEDLINE in 2006. A systematic review of Sørensen et al. (17) discovered 17 definitions and 12 conceptual models of HL. Based on all the offered, one overall definition was obtained, which reads: "HL is linked to literacy and entails people's knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course." There is currently no consensus on defining HL, which means that different approaches to this term are used in various research environments (17–20). An additional concept of understanding becomes a problem when it comes to assessing and measuring HL and then comparing these results between different studies (16). The presence of different definitions is probably due to the fact that the concept has been developed in different parts of the world, with varying abilities and skills considered necessary to deal with health information in each specific context (21).

In the twentieth century, reading and writing were sufficient to use information obtained from health professionals. However, with increasing expectations of active participation in health decisions, increasing responsibility for one's health, and digital development in health information, additional skills are needed to handle health information. First, the need for reading has increased, and the skills to apply and critically evaluate health information from various sources are essential. HL combines a set of skills or abilities, while on the other hand it depends on the requirements to which the individual is exposed. The impact of technological development has also increased, which will affect the definition and understanding of HL in the future (22).

Pharmacotherapy Literacy (PTHL)

Patients with chronic diseases need to continuously perform tasks associated with self-care and self-management of their medications. When taking medicines, they constantly need abilities related to various domains of HL, so HL brings together many concepts that are associated with patient's pharmacotherapy. Whether they rely on information in printed materials or verbal instruction patients with chronic conditions need to have adequate HL related to medications as critical for managing their conditions. Due to the complexity of the various procedures required for the adequate use of medications, the concept of PTHL was introduced.

King and colleagues, in consultation with the academy and pharmacists, formulated PTHL as: "*An individual's capacity to obtain, evaluate, calculate, and comprehend basic information about pharmacotherapy and pharmacy related services necessary to make appropriate medication-related decisions, regardless of the mode of content delivery (e.g., written, oral, visual images and symbols)*" (23). This definition was updated by adding to reduce thereby the risk of poor pharmacotherapy outcomes (24).

HL and PTHL in Persons With Type 2 Diabetes Mellitus

Diabetes is one of the most common chronic non-communicable diseases and is a major public health problem. In 2019, the International Diabetes Federation estimated that 463 million adults worldwide have diabetes and that this number is expected to increase to 700 million by 2,045. The cause of this disease is multifactorial, but it is associated with unhealthy lifestyles such as physical inactivity and poor diet. It is assumed that between 30 and 80% of people with type 2 diabetes are still undiagnosed. Complications such as diabetic nephropathy and neuropathy may occur at a later diagnosis of disease (25). Despite advances in therapy and the availability of clinical practice guides, only 30% of patients manage to achieve the target values of glycemia, cholesterol and blood pressure. The fact is that patients perform 95% of diabetes care on their own (26).

Type 2 diabetes is more common than type 1, so 90% of all diabetes is type 2 diabetes. It most often occurs in middle age and in the elderly. It is closely related to lifestyle and health habits, with being overweight and obese being risk factors. Hereditary factors can also influence the risk of developing this disease. Therapy includes weight loss, diet and therapy with drugs that lower blood glucose levels. Affected people are advised to give up cigarettes and reduce alcohol intake to prevent the appearance of cardiovascular diseases. Living with this disease requires changes in health behavior, self-control, and a lot of care (27–29). Since living with type 2 diabetes requires a lot from people with the disease, these persons must be informed about therapy, diet and other health behaviours, which require adequate HL and PTHL. Several international studies have shown that reading and understanding the guidelines for modern diabetes medications, applying appropriate dietary restrictions, and gaining insight into the physiological processes involved in the disease can be a major challenge for an individual (30, 31). The performing of diabetes self-management tasks frequently involves abilities, such as taking medications at the right time, interpreting blood glucose levels and calculating insulin doses.

A recent review of HL and health outcomes in patients with type 2 diabetes concludes that there is strong evidence to suggest a positive correlation between HL and diabetes knowledge (32). It is also considered that there is sufficient evidence to support a link between HL and self-care (33). On the other hand, the evidence of a link between HL and clinical indicators was inconsistent (34).

Some primary studies that looked at the level of HL in patients with type 2 diabetes found that a small number of these patients had adequate levels of HL (35–39).

Patients with diabetes and limited HL and PTHL often cannot read drug medication labels correctly, may misuse their medication, do not understand the meaning of consent forms, and generally have difficulty understanding printed care instructions and reading health advice and warnings (40–43). For this reason, is very important to assess their PTHL and in case of needs perform adequate training in order to improve control of their disease and pharmacotherapy management.

These patients also have poorer communication with doctors and participate less in making health decisions (4). Patients who are diagnosed have to make health decisions daily and must also perform complex self-care activities to keep the disease under control. Interventions in upgrading HL education and intensive diabetes-related education have shown good results in patients with limited HL to improve diabetes outcomes (44, 45). People with type 2 diabetes should undergo diabetes education programs at the time of diagnosis and then once a year. This education aims to enable individuals to participate in informed decision-making and disease control, all with the aim of better outcomes in treatment of this disease, improvement of glycemic control, prevention of complications and comorbidities, and improvement of quality of life (46). Education for diabetics should be evidence-based, have specific goals, and be tailored to the needs of individuals. However, the effectiveness of this education depends on individuals, i.e., characteristics such as age, gender, ethnicity, level of HL, ability to take care of themselves, all of which should be taken into account when planning and implementing this type of education (27, 47). In this way, they will be able to understand and use the information they receive to maintain health and control diabetes in everyday life (47).

Instrument Development

In the past 25 years, numerous instruments have been developed to measure HL and PTHL in various contexts (14, 24, 48). These instruments significantly differ in structure, measurement, range, and psychometric properties. The diversity of instruments has led to inconsistencies in measurement with the complexity of interpreting the results and choosing suitable instruments for new studies. Several studies have examined the variation through the range of the most used HL instruments (49, 50). Such variations can come from the fact that the instruments measure different conceptual dimensions of HL. However, it may be difficult for health professionals or researchers to choose the best instrument when they are unfamiliar with measurement properties. Another very important consideration in selecting a HL instrument is its mode of administration. In a subjective instrument, individuals self-report their perceived levels of literacy skills, such as using Likert scales. In contrast, an objective instrument is the interviewer-administrated instrument and assesses the ability to process information by asking respondents to answer specific questions, such as about the time to take the next medication. A subjective instrument requires less cognitive effort in responding to questions, whereas an objective instrument assesses health numeracy more accurately. A self-administrated instrument can be more practical in a very busy clinical settings, than interviewer-administered instrument.

Sometimes, the interviewer-administrated instrument may result in discomfort or embarrassment for patients who have a low HL.

Although the instruments were used in several populations, due to the complexity of the tasks and skills that people with type 2 diabetes require, their usefulness and applicability for this population remain challenging. With the growing interest in this construct, there has been an increasing demand for valid and reliable instruments for estimating HL and PTHL.

A systematic review of measurement properties has been designed for providing a comprehensive overview of the available instruments and identifying the best currently available instrument for general population (51). In the previous reviews of HL instruments methodological limitations were identified, such as being descriptive rather than systematic reviews, or lacking quality assessment or data synthesis (14, 52, 53). To address these limitations, a scoping review was conducted to systematically collect the literacy instruments used in people with type 2 diabetes and meet needs for understanding the characteristics, scope of measurements, and their applicability in this population.

METHODOLOGICAL STUDY DESIGN

Aim

This study aims to analyze instruments used in patients with type 2 diabetes mellites for measuring HL and PTHL, in relation to their characteristics (measurement scope, structure, domains, method of scoring), validation, strengths, limitations and accordingly to propose applicability of these instruments in clinical and research settings. This work can be useful as an inventory for researchers and practitioners who are seeking to identify validated measurement instruments in patients with type 2 diabetes mellitus and other chronic diseases that are fitting the best for their research and practice.

Materials and Methods

Authors built a search strategy by using the PICOS questionnaire. During November and the first 2 weeks of December 2020, a systematic search of the Scopus and PubMed databases was performed in search of peer-reviewed literature of patients with type 2 diabetes mellitus. The protocol of this systematic review (including the article identification strategy and data collection form, etc.) mainly referred to the Cochrane Handbook for Systematic Reviews of Interventions (54) and the reporting of this systematic review was based on the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (55).

Search Strategy

The keywords used were: "medication literacy," "measurement tool," "assessment," "patient," "chronic diseases" and "healthcare system." A search of the terms above found that the number of articles specifically mentioning PTHL was limited, so the search was extended to articles mentioning "health literacy" combined with patients with type 2 diabetes.

In the articles obtained by this search, the references were manually checked to identify additional articles of importance for the work.

Study Screening and Selection

All original articles in English are taken into consideration, which meet the below criteria. Duplicates have been excluded. The evaluation of studies regarding the inclusion and exclusion criteria was performed by a pair of independent reviewers (ML and DK): (1) review of titles and abstracts of articles related to the topic (2) review of complete articles was done which examined the HL and PTHL of patients with type 2 diabetes and had the original results of the health and pharmacotherapeutic literacy of patients with type 2 diabetes mellitus conducted through appropriate questionnaires. After cross-checking, a third reviewer (NBS) resolved cases of disagreement.

Inclusion and Exclusion Criteria

Peer-reviewed papers with cross-sectional studies, longitudinal studies and cohorts were included if they were: published between the period 2006–2021, written in English, involved patients with type 2 diabetes and papers in which HL and PTHL were examined in patients with type 2 diabetes.

The exclusion criteria were: reviews, case reports, book chapters, letters, editorials, studies that did not address HL and PTHL among patients with type 2 diabetes, studies that did not use the questionnaire for assessing literacy, studies not available or not published in English.

The inclusion and exclusion criteria are presented in **Table 1**.

Data Extraction and Synthesis of Results

Data extraction was performed independently by the authors. They extracted different characteristics from each publication, such as (i) publication information: author and year; (ii) study characteristics: country, setting, population, number of participants and results in terms of HL and PTHL (iii) HL and PTHL instruments: name, dimensions, number of items, purpose, target population, administration mode, validation process, scoring, cut-off points, strengths and limitations.

The studies were grouped according to instruments used for the measurement of literacy: HL and PTHL. A descriptive synthesis of the identified studies was performed, and variables described in the synthesis include number of participants, setting,

TABLE 1 | Inclusion and exclusion criteria.

	Inclusion criteria	Exclusion criteria
Population	Patients with type 2 diabetes mellitus	Patients with other diseases
Type of the study	Cross-sectional, longitudinal, Cohort	Reviews, case reports, book chapters, letters, editorials
Instruments	Using the questionnaire for accessing health/and pharmacotherapy literacy	Works that did not use the questionnaire for accessing literacy (health/and pharmacotherapy)
Language	English	Studies not available or not published in English
Other	Availability of abstract The full text available Year of publication > 2006	Unavailability of abstract The full text not available Year of publication < 2006

country, population and results. Formal analysis of the results was a descriptive synthesis of the identified instruments from selected studies to determine instruments key characteristics including identifying domains, length of tool (number of questions/items/domains), time for completion, format, and psychometric properties.

Critical Appraisal

At the time of our research, there were no accepted quality assessment instruments for cross-sectional studies (56), authors decided to choose a relatively widely used scale, the Agency for Healthcare Research and Quality scale (AHRQ scale) with 11 items, each of which was answered with "yes," "no" and "unclear." Two researchers (DK and ML) independently evaluated the quality of the included articles using the AHRQ scale. Any disagreements after cross-checking were resolved by discussions between the two researchers with the final decisions of the third researcher (NBS). If the answer was "no," "unclear" or "not applicable," the item was given a score of "0"; if the answer was "yes," the item was scored as "1." The quality assessments of the articles were classified as follows: low quality = 0–3, medium quality = 4–7, high quality = 8–11 (57).

The quality assessment of the identified studies is presented in **Table 2**. The majority of them were classified with medium quality and one fulfilled the criteria for high.

RESULTS

Study Screening and Selection

The PRISMA flow chart in **Figure 1** summarises the results of the search process. 1. A search obtained 5,874 potentially relevant studies, while 8 were found by reference review. A cursory review of the content of the papers left 356 papers for further evaluation. Further exclusion (after reading the abstracts and methodology) was based on the principle of excluding papers that mentioned the instrument for assessing HL and PTHL, but without analyzing its structure, and excluding papers that are duplicates (same author, same instrument) left 111 articles for full reading, of which the final number of included studies was 24.

The comparison method was used to compare the instrument in terms of their structure (number and type of questions), the way of reporting, version, purpose, place where they were developed, target population, the person who developed it, year of publication, scoring, heath literacy domains, time and way for administration, measurement scope, validation, strengths, and limitations.

A thorough analysis has been presented in the **Tables 3**–**5**. **Tables 3**, **4** present the instruments used in the studies to assess HL and PHTL, their basic characteristics: domains, methods of assignment, structure and method of scoring. **Table 5** shows the psychometric characteristics of the instruments, strengths and limitations.

Instrument Characteristics

The identified instruments used for assessing the level of HL and PTHL in extracted works are the following: Korean Functional Test HL (1 study), Newest Vital Sign, NVS (1 study), Functional, Communicative and Critical Health Literacy scale, FCCHL (1 study), Health Literacy Survey European Questionnaire 47, HLS-EU-47 (1 study), Test of Functional Health Literacy in Adults, TOFLHA (1 study), Test of Functional Health Literacy in Adults–Short Form, S-TOFHLA (8 studies), Rapid Estimate of Adult Literacy in Medicine–Revised, REALM-R (1 study), 3 brief screening questions, 3-brief SQ (6 studies), Rapid Estimate of Adult Literacy in Medicine, REALM (3 studies), Health Literacy Questionnaire, HLQ (1 study) and Diabetes Numeracy Test 15, DNT-15 (1 study) (37, 58–80). There are considerable differences found in their structure, number of items, administration time, available languages, type of administration, scoring system, measurement scope and properties, implicating their use in different settings.

The most used measures of HL in patients with type 2 diabetes mellitus were S-TOFHLA, then 3-brief SQ, REALM and HLS-EU-47. The S-TOFHLA, TOFHLA and REALM have been validated in different populations and are used in validation studies for 3-brief SQ and NVS. They are considered as a gold standard in validation studies. However, 3-brief SQ and NVS have a broader measurement scope and better properties, which put them in a better position for use in future validation studies. S-TOFHLA, REALM and HLS-EU-47 are not practical in busy clinical settings and REALM requires researcher participation. While the most used instruments, S-TOFHLA and REALM, measure only the functional domain of HL, the others 3-brief SQ, and HLQ address functional and critical HL, and DNT-15, KHLS and TOFHLA functional HL and numeracy. The only one for examination of all three levels of HL individually, their mutual correlation and different effects on patient is FCCHL.

Validation, Strengths, and Limitations

NVS - Good reliability and convergent validity with well-validated and commonly used measures of HL such as the TOFHLA. Strengths are related to its suitability for rapid assessment of low HL. Test format might intimidate respondents.

FCCHL - Strong positive evidence for its content and structural validity and moderate positive evidence for internal consistency. This scale includes three levels of HL, each of which might have different effects on patient outcomes. It is proved to be easy to administer in a clinical setting. The scale is not validated in English.

Three-brief SQ - Positive evidence for the criterion validity of the 3-SQ with the S-TOFHLA (36 items) and limited negative evidence for its hypothesis testing validity and internal consistency. Instrument is validated in several diverse sample populations. It is quick, easy, and inexpensive for administration. Limitation is related to self-assessment and potential for self-report bias.

HLS-EU-47 - High levels of internal consistency reliability. It is available in many languages, length of assessment increases response burden.

S-TOFHLA - Demonstrated evidence for the internal consistency due to there being no evidence of structural validity. It has been validated in several diverse populations. Lack of this instrument is that it may not capture an individuals' HL in the dimension of numeracy.

TABLE 2 | Critical appraisal of identified studies: quality assessment.

References	Questions											Quality of studies
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	
Klinovszky et al. (58)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Hashim et al. (59)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Gomes et al. (60)	1	1	1	0	0	1	0	0	0	1	0	5 medium
Finbråten (61)	1	0	1	1	0	1	0	0	1	1	0	6 medium
Tseng et al. (62)	1	0	0	1	0	0	0	0	0	1	0	3 low
Friis et al. (63)	1	0	1	1	0	0	0	0	0	1	0	4 medium
Sayah et al. (64)	1	1	1	1	0	1	0	1	1	1	0	8 high
Thurston et al. (65)	1	1	1	1	0	0	0	1	0	1	0	6 medium
Mantwill et al. (66)	1	1	1	1	0	0	0	1	0	1	0	6 medium
van der Heide et al. (67)	1	0	1	1	0	1	0	0	1	1	0	6 medium
Sayah et al. (68)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Bauer et al. (69)	1	0	1	1	0	0	1	0	0	1	0	5 medium
Coffman et al. (70)	1	1	1	1	0	0	0	0	0	1	0	5 medium
McCleary-Jones, (71)	1	1	1	1	0	0	1	0	0	1	0	6 medium
Glasgow et al. (72)	1	1	1	1	0	1	0	0	0	1	0	6 medium
Bains et al. (73)	1	1	1	1	0	1	0	0	0	0	0	5 medium
Mancuso, (74)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Osborn et al. (37)	1	1	1	1	1	1	0	1	0	1	0	8 high
Sarkar et al. (75)	1	1	1	1	0	0	1	1	0	1	0	7 medium
Mbaezue et al. (76)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Kim, (77)	1	1	1	1	0	0	0	0	0	1	0	5 medium
Ishikawa et al. (78)	1	0	1	1	1	0	1	0	0	1	0	6 medium
Gebretsadik et al. (79)	1	1	1	1	0	0	1	1	0	1	0	7 medium
Morris et al. (80)	1	0	1	0	0	1	0	0	0	1	0	4 medium

Q1: Define the source of information (survey, record review) Q2: List inclusion and exclusion criteria for exposed and unexposed subjects (cases and controls) or refer to previous publications Q3: Indicate time period used for identifying patients Q4: Indicate whether or not subjects were consecutive if not population-based Q5: Indicate if evaluators of subjective components of study were masked to other aspects of the status of the participants Q6: Describe any assessments undertaken for quality assurance purposes (e.g., test/retest of primary outcome measurements) Q7: Explain any patient exclusions from analysis Q8: Describe how confounding was assessed and/or controlled Q9: If applicable, explain how missing data were handled in the analysis Q10: Summarize patient response rates and completeness of data collection Q11: Clarify what follow-up, if any, was expected and the percentage of patients for which incomplete data or follow-up was obtained.

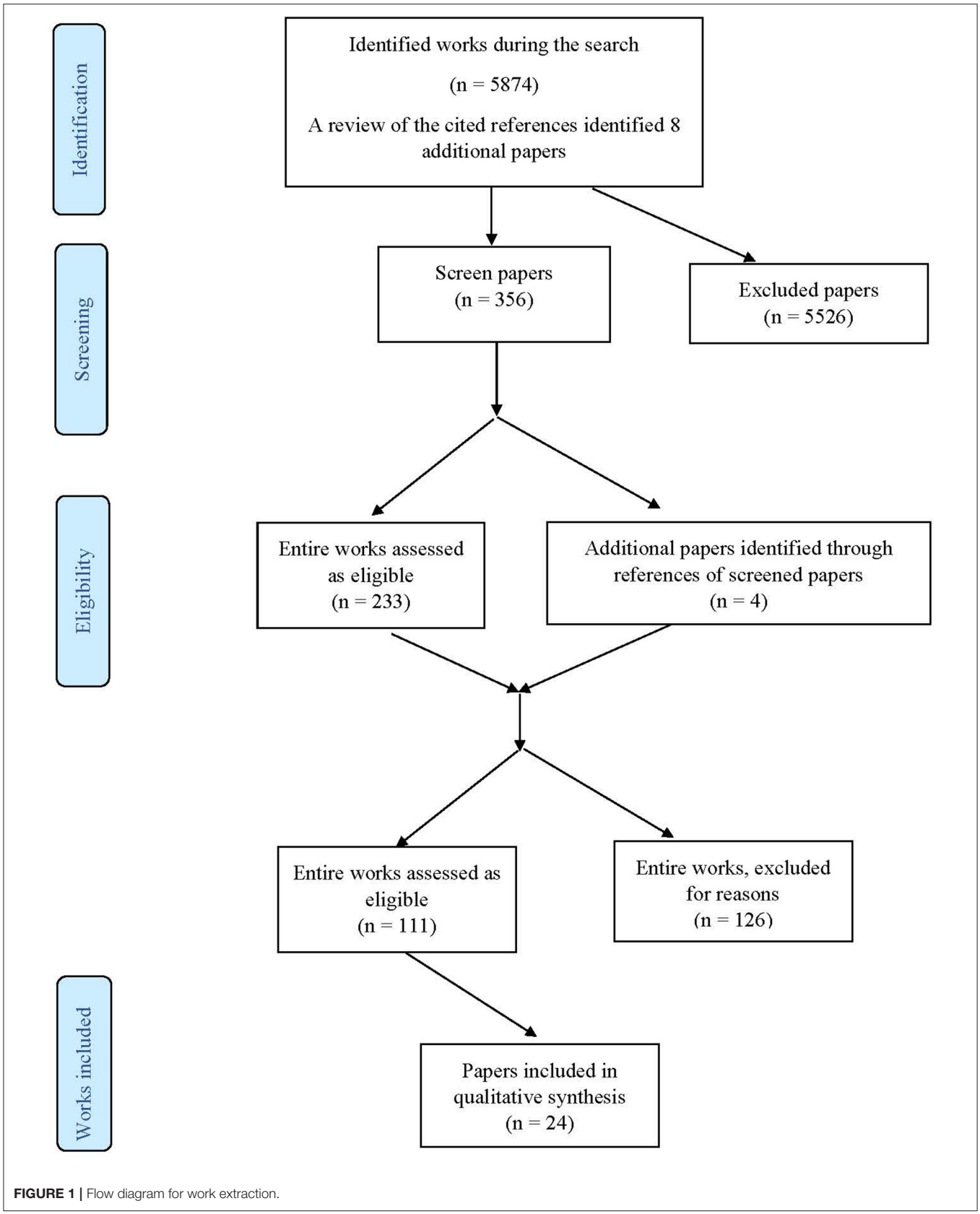

FIGURE 1 | Flow diagram for work extraction.

TABLE 3 | Basic characteristics of the included studies for health literacy.

Name of the instrument	Objective/ Subjective (Self-reported)	Version	Purpose of the instrument	Where it was developed/target population	Who developed the instrument/ Year of publication/ reference	Version in language
3-brief SQ	Self-reported	Short version	Self-report of confidence in HL skills	USA/Adults	Chew et al. (49)	English
KHLS	Objective	Original	Screening test for limited HP for older Korean adults	Korea/Older Korean adults	Lee et al. (81)	Korean
FCCHL	Objective	Original	Self-report of HL skills	Japan/Adults	Ishikawa et al. (78)	Japanese
HLS-EU-Q47	Self-reported	Original	Questionnaire to assess the relation between abilities, system demands, and decision making	Greece, Ireland, and the Netherlands/15+ years	Sørensen et al. (82)	Available in more than 10 languages
NVS	Objective	Original	Information presented on a nutrition label for reading, comprehension, and numeracy	USA/Adults	Weiss et al. (83)	Spanish, Japanese, Dutch, Turkish, Chinese, Croatian, Italian and Brazilian
TOFHLA	Objective	Original	Close style reading comprehension of health-related content	USA/Adults	Parker et al. (84)	English, Spanish, Chinese, French, German and Italian
S-TOFHLA	Objective	Short version	To measure patients' ability to read and understand health-related materials	USA/Adults	Baker et al. (85)	English, Spanish, French, German and Italian
REALM	Objective	Original	A rapid screening tool to help physicians to identify patients with reading disabilities and assess reading levels	USA/Adults	Davis et al. (86)	English
REALM-R	Objective	Revised form	Word recognition and pronunciation test	USA/Adults	Bass et al. (87)	English
HLQ	Self-reported	Original	Survey items for measuring health literacy of individuals	Australia/Adults	Osborne et al. (88)	English
DNT-15	Objective	Short version	Reading recognition, spelling, and arithmetic computation	USA/Adults	Huizinga et al. (89)	English, Spanish

3-brief SQ, 3 brief screening questions; KHLS, Korean functional Health Literacy Test; FCCHL, Functional, Communicative and Critical Health Literacy scale; HLS-EU-Q4 7, Health Literacy Survey European Questionnaire47; NVS, Newest Vital Sign; TOFHLA, Test of Functional Health Literacy in Adults; s-TOFHLA, Test of Functional Health Literacy in Adults–Short Form; REALM, Rapid Estimate of Adult Literacy in Medicine; REALM-R, Rapid Estimate of Adult Literacy in Medicine–Revised; HLQ, Health Literacy Questionnaire; DNT, Diabetes Numeracy Test.

REALM - Found to have a high test-retest reliability of 0.99. It is assessed by healthcare professionals and was found to have good face validity; however, it lacks in construct validity. It is quick and easy for administration, limited to the ability to pronounce words without being able to measure the patient's ability to understand the instructions on labelling of prescribed drug.

HLQ - Positive moderate evidence for its content validity and internal consistency and unknown evidence for structural validity. Strength is that measures multiple domains of HL, but due to self-assessment has a potential for self-report bias.

DNT - Moderate evidence for its content validity and internal consistency and limited positive evidence for structural validity. This is test numeracy that is associated with diabetes management. Limitation is that can be difficult or require high numeracy skills (49, 78, 81–89).

Health Literacy and Pharmacotherapy Literacy

Preliminary data in relation to HL and PTHL were extracted from the studies included in the qualitative synthesis and summarized in **Table 6** (for HL) and **Table 7** (for PTHL).

In the research period most of the studies were published in the period from 2006 to 2021 (37, 58–80). The largest number of studies was conducted in the United States (11 studies) and Canada (2 studies). In contrast, in South Korea, Japan, Switzerland, Taiwan, Spain, Norway, Brazil, Denmark,

TABLE 4 | Basic characteristics of the included studies for pharmacotherapy literacy.

Name of the instrument	Scoring	Heath literacy domains	Time for administration	Measurement scope	Total number of items	Who administers the tool
3-brief SQ	Values of 0, 1, 2, 3, and 4 are assigned to each response option for each question; Score ranges from 0 to 12; High scores = high HL skills; Low scores = low HL skills	Functional and critical HL	1–2 min	Reading and understanding health information, completing medical and health care form	3	Self-administered or researcher administered
KHLS	Sum score	Functional HL and numeracy	15–20 min	Literacy, interaction, comprehension, numeracy, information seeking, application and decision making	24	Researcher administered
FCCHL	Each item is scored on a 4-point scale ranging from 1 (*never*) to 4 (*often*); The scores of the items are summed up and divided by the number of the items in the scale. Higher scores indicate higher HL level	Functional, communicative, and critical HL	5–6 min	Reading, understanding applying health information and communication with health care providers	14	Self-administered or clinician/ researcher administered
HLS-EU-Q47	The 47 items are adapted to a 50-point scale: 0–25: inadequate health literacy. 26–33: problematic health literacy; 33–42: sufficient health literacy; 42–50: excellent HL	Functional HL	12–15 min	Interaction, comprehension, information seeking, application, decision making and evaluation	47	Self-administered
NVS	Each item answered correctly is given a score of 1. Scores range: 1–6 (score <4 = limited HL)	Functional, critical HL and numeracy	3 min	Reading, understanding, and applying health information	6	Self-administered
TOFHLA	Scores range 0–100: <60 = inadequate HP; 60–75 = marginal HL; >75 = adequate HP	Functional HL and numeracy	22 min	Reading, understanding applying health information and communication with health care providers	50	Self-administered
S-TOFHLA	Scores range 0–36: 0–16 = inadequate HL; 17–22 = marginal HL; 23–36 = adequate HL	Functional HL	7 min	Applying health information and communication with health care providers	36	Self-administered
REALM	Grade is assigned based on total score that ranges from 0 to 66: 0–18 = ≤ 3rd grade, 19–44 = 4th-6th grade, 45–60 = 7th-8th grade; 61–66 = ≥9th grade	Functional HL	<3 min	Reading and understanding health information	66 words	Researcher administered
REALM-R	Grade is assigned based on total score that ranges from 0 to 8. Score ≤6 corresponds to 6th grade and indicates poor HL	Functional HL	<2 min	Reading and understanding health information	8 words	Researcher administered
HLQ	Independent scales that measure proportions of nine competencies for HL	Functional and critical HL	5–10 min	Interaction, comprehension, information seeking, application and decision making	44	Self administered
DNT-15	Items are scored as binary outcomes: correct or incorrect. Scores are reported as percent correct (with a possible range of 0% to 100%)	Functional HL and numeracy	10–15 min	Reading and understanding health information	15	Researcher administrated or self administered

Iraq, Netherlands and Hungary, one study was performed. Cross-sectional studies make up the majority (20 studies), while three are longitudinal and one is a cohort study. The sample size ranged from at least 50 to 46,354 subjects and are adults over the age of (37, 58–80).

In six studies, limited HL was observed in <50% of subjects, and in five studies, more than 50% of subjects had limited HL. HL levels have been linked to diabetes knowledge and treatment efficacy, while HbA1C concentrations, Internet use, glycemic control, and health consequences have not been linked to HL

TABLE 5 | Instruments' validation, sterngts and limitations.

Name of the tool	Validation	Strengths	Limitations
3-brief SQ	Tested against STOFHLA, items AUROC curve ranged from 0.76 to 0.87 (95% CI). The grouped items, including a fourth item about verbal information, (BRIEF), demonstrated an AUROC curve of 0.79 (95% CI) for identifying inadequate skills. Correlations as grouped items against S-TOFHLA (0.42) and REALM (0.40) in multiple demonstrating moderate correlation.	The instrument is validated in several diverse sample populations. It is quick, easy, and inexpensive for administration. Functional domains associated with inadequate HL are assessed. Less likely to induce anxiety and shame.	Methods typically relied on convenience samples. Self-assessment has potential for self-report bias.
KHLS	The overall fit of the two-factor model of the scale was assessed by root mean square error of approximation (0.039), indicating a good fit (criterion 0.05 or less) with an internal consistency of 0.89.	Measure uses questionnaire format containing short passages, pictures, and graphs with multiple-choice answer format, providing a skills-based approach to measurement. Authors used factor analysis methods for development.	No concurrent validity assessed due to lack of a comparative instrument. 10% of study participants needed assistance from interviewers.
FCCHL	Reliability: Cronbach's α: Overall scale: 0.78; Functional domain: 0.84; Communicative domain: 0.77; Critical domain: 0.65	This scale includes three levels of HL, each of which might have different effects on patient outcomes. It is proved to be easy to administer in a clinical setting.	HL was measured based on a self-reported questionnaire. Individuals with reading problems are often ashamed and hide their inability to read, which might have led to an overestimation of the HL levels. Not validated in English.
HLS-EU-Q47	Correlated with NVS (0.25). A multivariate linear regression model with the total sample measured the relation between social variables and health literacy yielding an adjusted R2L17.4%, pL.00. Financial deprivation was the strongest predictor of health literacy.	Available in many languages. Comprehensive, conceptual based measure of most dimensions of health literacy.	Self-assessment has potential for self-report bias. Length of assessment increases response burden.
NVS	Reliability of Cronbach's alpha in English (0.76) and on Spanish (0.69) and correlates with TOFHLA (0.49). The AUROC curve is 0.88 for the English version and 0.72 for the Spanish version.	The NVS test is suitable for rapid assessment of low HL.	Validation sample did not fully represent a demographically diverse population. Test format might intimidate respondents.
TOFHLA	Reliability: Cronbach's α: 0.98; Validity: 0.84 (with REALM),.0.74 (with WRAT-R)	It has been validated in several diverse populations. Available in different languages.	Long version is time consuming. This version is more useful as a research tool than a clinical screening tool.
S-TOFHLA	Reliability: Cronbach's α: 0.98; Validity: 0.91 (with TOFHLA), 0.80 (with REALM)	Short version is available. It has been validated in several diverse populations.	It may not capture an individuals' HL in the dimension of numeracy.
REALM	Correlated with WRAT-R2 ($r = 0.82$) WRAT-R3, (0.88); SORT-R, (0.95, 0.96); PIAT-R, (0.94, 0.97); TOHFLA, (0.30, 0.84). Test-retest correlation: test-retest reliability 0.98 and 0.99.	It is quick and easy for administration. It is short, can be easily administered with minimal training, and it's strongly correlated with standardized literacy assessments.	Only measures one dimension of HL. Limited to the ability to pronounce words without being able to measure the patient's ability to understand the instructions on labeling of prescribed drug.
REALM-R	Reliability: Cronbach's α: 0.91. Validity:0.72 (with REALM), 0.64 (with WRAT-R)	A promising tool for the rapid assessment of HL in a busy clinical practice to screen for potential literacy problems.	Only measures one dimension of HL. Presence of a ceiling effect. Does not measure the patient's understanding of the words.
HLQ	A nine-factor model was fit using 44 final items with no cross-loadings or correlated residuals. The fit was satisfactory CFI = 0.936 = 0.930, RMSEA = 0.076, and WRMR = 1.698. Correlations between factors showed a clear distinction between the agree/disagree scales, but less distinction for cannot do/very easy scales.	It measures multiple domains of HL.	Self-assessment that has a potential for self-report bias.
DNT-15	Correlated with REALM (0.54), WRAT (0.62), and Diabetes Knowledge Test (0.71); Internal reliability (0.95). It has good internal reliability (0.90 and 0.89); split sample analysis, correlated with the full DNT in both subsamples (0.96 and 0.97).	Tests numeracy is associated with diabetes management.	Validated in highly educated sample and resulted in mean score correct of 61%—may be difficult or require high numeracy skills.

TABLE 6 | Basic characteristics of the included studies for HL1.

Instrument	Coutry	Sample size	Results	References
S-TOFHLA	USA	1,002	HL levels have not been associated with glycemic control or the health consequences of type 2 diabetes	(80)
REALM	USA	398	HL levels were not associated with HbA1C blood levels	(79)
FCCHL	Japan	138	The three HL scales were only moderately correlated with each other, suggesting that each represents a different domain of HL abilities and skills.	(78)
KHLS	South Korea	103	71.7% of patients had limited HL	(77)
S-TOFHLA	USA	189	HL was not associated with blood glucose measurement, but was associated with recording of glucose measurement	(76)
3-brief SQ	USA	14,102	Patients with limited HL were less likely to log on to the patient portal	(75)
TOFHLA	USA	102	36.3% of patients had limited HL	(74)
S-TOFHLA	USA	250	The level of HL has not been linked to the use of the Internet	(72)
S-TOFHLA (Spanish)	Spain	144	46.5% of patients had limited HL	(70)
3-brief SQ	USA	1,366	72% of patients had limited HL	(69)
3-brief SQ	Canada	154	Limited HL has been observed in patients with type 2 diabetes who have also been diagnosed with depression	(68)
3-brief SQ	Netherlands	1,714	Lower HL was significantly associated with less diabetes knowledge, higher HbA1c level, less self-control of glucose level, and less physical activity	(67)
3-brief SQ (1 question)	Switzerland	493	8.7% of patients had limited HL	(66)
S-TOFHLA	USA	288	32.8% of patients had limited HL	(65)
3-brief SQ	Canada	1,948	12.6% of patients had limited HL	(64)
HLQ	Denmark	46,354 of which 1,685 participants were diagnosed with diabetes	Even after adjusting socio-demographic characteristics, people with diabetes and limited HL were more likely to be physically inactive and had unhealthy eating habits compared to people with high levels of HL	(63)
NVS	Taiwan	232	76.3% of patients had limited HL	(62)
HLS-EU-Q47 FCCHL	Norway	388	Good general health, education and empowerment were positively associated with HL in people with T2DM. They explained about 17% of the total variance in HL	(61)
S-TOFHLA	Brazil	347	A significant number of patients did not have adequate HL	(60)
S-TOFHLA	Iraq	280	Most subjects had limited HL and poor glycemic control	(59)

levels (37, 58–80). One study found an increased prevalence of people with limited HL who were diagnosed with depression (67), while another study found that people with limited HL were more likely to eat unhealthily and had reduced physical activity compared to people with high HL (62).

DISCUSSION

This work presents the most comprehensive inventory of HL and PTHL measures in patients with type 2 diabetes mellites to date. There are limited number of works assessed the instruments that measure HL in patients with type 2 diabetes and they were focused only on available self-administered instruments in regards of validation aspects (90), however this work presents the broader perspective including the more comprehensive report on their structure, measurement scope, scoring etc. allowing possibilities for clinicians, health professionals and researchers to evaluate available HL and PTHL instruments and match them with the goals of their work.

HL has been presented as a measurable and important concept in considering education for patients with chronic diseases such as diabetes. It has been shown that in comparation to the other scales that focus exclusively on functional HL, FCCHL covers all three levels of HL, each of which can have different effects on patient outcomes. Also, the scale is easy to apply in clinical conditions (61).

The identified instruments have inherent strengths and weaknesses as a result of their structure, properties and measurement scope. The REALM, NVS, TOFHLA/ s-TOFHLA, DNT, KHLS, FCCHL and NVS are designed to directly measure specific skills and have some limitations in administration, especially in clinical settings where they are more likely to cause anxiety and shame among patients with inadequate HL

TABLE 7 | Basic characteristics of the included studies for pharmacotherapy literacy.

Instrument	Coutry	Sample size	Results	References
S-TOHFLA DNT-15	Hungary	102	34.6% of the patients with T2DM had inadequate/marginal reading and comprehension level	*(58)
REALM	USA	383	The level of HL has been linked to the effectiveness of patient treatment	(37)
REALM-R	USA	125	HL levels have been linked to the level of diabetes knowledge, but have not been linked to glycaemia or medication	(73)
REALM	USA	50	The level of HL has been linked to level of knowledge about diabetes	(71)

**Accessing both–health and pharmacotherapy literacy.*

and PTHL skills. Self-administrated instruments such as 3-brief SQ, HLS-EU-47 and HLQ non-directly measure certain skills and they are less likely to cause the anxiety and shame which makes them more suitable to be used in clinical settings and research applications. Many self-reported measures are designed as screening tests that may be differentially sensitive and specific than measures developed to more fully describe HL for research or clinical purposes. This is also seen in other articles (21, 91, 92).

The NVS had good sensitivity and may be more sensitive than the TOFHLA for marginal HL (83). Using the test can alert physicians and pharmacists to focus on the patients who require more attention and help them communicate with those patients by using recommended techniques.

The REALM and the TOFLHA focus primarily on reading-related skills and therefore do not present comprehensive measures for the skills needed by individuals in the healthcare system (21).

Time of administration plays a significant role in clinical settings. In this regard 3-brief SQ, NVS, FCCHL, REALM, REALM-R, S-TOFHLA and HLQ are relatively quick and easy for an administration and can be considered in different clinical settings and survey researches.

The type of administration must also be considered for practicality in clinical settings. REALM, REALM-R, KHLS and DNT-15 require involvement of the researcher and could cause shame and discomfort. Since self-administered instruments TOFHLA, S-TOFHLA, NVS, HLS-EU-47 and HLQ are very unlikely to cause discomfort, they require good visual abilities, full concentration, and good writing skills. Three-brief SQ and FCCHL can be administered in both ways and are more flexible and convenient for use.

A lack of researches with PTHL questionnaires in patients with type 2 diabetes mellitus is a very limiting factor for this population since the use of multiple drugs/insulins is very common. REALM only measures one dimension of HL and does not assess the patient's understanding of the words. DNT-15 is the test for numeracy.

The findings of this review can be used for other chronic conditions with similar HL and PTHL demands on individuals. This review did not only address the usefulness and applicability of the instruments in individuals with diabetes but also provided an evaluation of these instruments and their strengths and weaknesses, which are transferable for evaluating their applicability in other health conditions and situations.

Practice Implications

As instruments for measuring HL and PTHL continue to be published, authors advise clinicians, health professionals and researchers to evaluate available HL and PTHL measurements for a conceptual and practical match with the goals of their work.

When choosing a practical match, style of administration, purpose for measurement, their basic characteristics: domains, methods of assignment, structure, method of scoring, validation, strengths and limitations should be considered. It is important to align with the topic or task under consideration and choose the one that has been validated in a similar target population in order to have an accurate measure of the domain being assessed. Predictive qualities and appropriateness for assessment of changes in HL and outcomes over time have to be taken under consideration.

FCCHL was evaluated as the most appropriate instrument to apply to people with diabetes since a diabetes-specific type of instrument and the contents of its items may be more sensitive in a diabetes clinical setting targeted at diabetes, it is a model-based and comprehensive measure which covers all 3 levels of HL and the evidence for the measurement properties are better than those for the other instruments. However, his structural validity needs to be further established, and therefore adding DNT-15 questionnaire can be one of the options for considering application of FCCHL in this population (90).

Based on the previous considerations FCCHL and 3-brief SQ have the broadest measurement scopes. They are quick, easy, and inexpensive for administration. Three-level HL can be considered as the most useful and comprehensive instrument to screen for inadequate HL. The limitation is that the English version is not validated. Three-brief SQ has many advantages in comparison to other instruments, including that it is less likely to cause anxiety and shame. This instrument can be considered the best for measuring functional HL in patients with diabetes mellitus type 2 and other chronic diseases.

Limitations

This review was subject to some limitations. The use of non-interventional studies, the heterogeneity of studies in terms

of samples represent important limitations for this scoping review. Only works written in English have been considered. Assessments of the instruments' dimensions, strengths, and limitations were made on the basis of our own experience and judgment; and as such, this was a subjective review. In order to minimize the effect of the issue of subjectivity, each measure was analyzed by multiple authors, and any discrepancy was addressed by all the authors and resolved through fruitful discussion.

CONCLUSION

The ongoing development of instruments suggests that there is still a need for comprehensive measurement across diverse populations. Three-brief SQ has been found convenient for use in populations with diabetes mellitus type 2 taking into consideration the broadest measurement scope, demonstrated good measurement properties, that has many advantages over other instruments, and could be considered the best available instrument to measure functional HL. FCCHL scale measures the broader concept of HL, including the ability to retrieve, understand, and use health-related information and could be one of the most appropriate and comprehensive instrument for measuring HL in people with diabetes. However, it has not been validated in English and the future research must be directed in this way, as well as establishing of the structural validity of the questionnaire.

The results of the studies show that HL may be directly related to the clinical outcome in patients with diabetes and that each individual level of HL could act differently. The ways in which each level of HL influences patient behaviour about care and health outcomes should be further explored.

So far, PTHL questionnaires (REALM/R and DNT-15) have not found their best application in people with type 2 diabetes mellitus and further research should certainly be aimed at developing a specific PTHL questionnaire for people with type 2 diabetes mellitus, due to the nature of the disease itself and the frequent use of multiple drugs in its therapy.

This works provides information to enable practitioners, health professionals and researches to select the most appropriate instrument available for measuring HL and PTHL in patients with type 2 diabetes mellitus.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

DK and ML contributed substantially to the conception, design of the study, screening, and selection of the studies. ML produced the first draft of the paper, which was extensively redrafted by DK, with significant input from NB-S. All authors contributed to the interpretation of data and read and approved the final manuscript.

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Article

Cross-Cultural Adaptation and Validation of the Functional, Communicative and Critical Health Literacy Instrument (FCCHL-SR) for Diabetic Patients in Serbia

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Abstract: Thoroughly validated instruments can provide a more accurate and reliable picture of how the instrument works and of the level of health literacy in people with type 2 diabetes mellitus (T2DM). The present work aimed at cross-cultural adaptation and validation of the Functional, Communicative and Critical Health Literacy Instrument (FCCHL) in patients with T2DM in Serbia. After translation and back-translation, views from an expert group, one cognitive interview study (n = 10) and one survey study (n = 130) were conducted among samples of diabetic patients. Item analysis, internal consistency, content validity, confirmatory factor analysis (CFA) and reliability testing were performed. When all 14 items were analyzed, loading factors were above 0.55, but without adequate model fit. After removing two items with the lowest loadings FHL1 and IHL2 the fit indexes indicated a reasonable normed χ^2 (SB scaled χ^2/df = 1.90). CFI was 0.916 with SRMR = 0.0676 and RMSEA = 0.0831. To determine internal consistency, Cronbach's alpha coefficient was 0.796 for the whole FCCHL-SR12. With only minor modifications compared to the English version, the 12-item FCCHL instrument is valid and reliable and can be used to measure health literacy among Serbian diabetic patients. However, future research on a larger population in Serbia is necessary for measuring the levels of HL and their relationship with other determinants in this country.

Keywords: translation and cultural adaptation; confirmatory factor analysis; perception-based outcome measurement instrument; generic scale; self-reported; subjective measurement; chronic non-infectious diseases

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1. Introduction

During the last three decades, the importance of Health Literacy (HL) and optimal health outcomes has been recognized [1–5]. HL has been given a prominent place in some important documents issued by the World Health Organization (WHO) and the European Union (EU) [6,7]. There are several definitions and conceptual models of HL [8–11], the most commonly cited definition is from 2000 where Ratzan and all define HL as: "the degree to which individuals have the capacity to obtain, process, and understand basic health information and the services needed to make appropriate health decisions" [12].

The definition of HL was revised in August 2020 with the publication of the U.S. Government's Healthy People 2030 external icon initiative. Audit involves the division of HL into personal HL and organizational HL and provides the following definitions: Personal health literacy is the degree to which individuals have the ability to find, understand and use information and services to inform health decisions and actions for themselves and others. Organizational health literacy is the degree to which organizations fairly enable individuals to find, understand, and use information and services to inform health decisions and actions for themselves and others [13].

Although there are different definitions of health literacy it has been proven that people with low levels of health literacy have less compliance with medical information and drugs, increased but inefficient use of the health system, more visits to the emergency center, higher use of drugs, and a higher risk of death [14–17]. In addition to the negative effects, low health literacy is both an economic burden on society and an alarming public health problem [2]. Among the elderly, people with low socio-economic status and minority groups, the greater presence of low health literacy has been reported, which significantly contributes to health inequalities [16]. Low health literacy is linked directly or indirectly to a large number of poor health outcomes. Data show that there is a correlation between low health literacy and reduced use of available health information and services. This is reflected in a greater need for health education and use of preventive health services [18,19].

It is extremely important to properly measure HL skills in order to gain insights into the level of patients' HL. However, so far, a lot of available instruments show several problems. First, they usually have to be used by a healthcare professional, which is time consuming and impracticable in clinical practice. Second, the basic constructions and the content of existing instruments varies, and only a few instruments are based on the proposed definitions and models of health literacy. Finally, most existing HL measures are focused primarily on understanding reading, while health literacy considers more than functional literacy, namely abilities for constructive use of information [20,21].

A theoretical model which is cited in the professional literature and useful in analyzing the literacy abilities required in various health situations is the Nutbeam model. This model distinguishes three types of health literacy: functional (FHL), communicative/interactive (IHL) and critical health literacy (CHL). Each of these types of health literacy requires different skills for obtaining, understanding, and using information. FHL represents the basic level of reading and writing necessary for living effectively in everyday situations. IHL considers more advanced cognitive and writing skills, which, together with social skills, allow people to extract information, derive meaning from various forms of communication and apply new information when circumstances change. CHL presents more advanced skills for analysis of data from critical perspective and using information to exert greater control over life events and situations [22].

Ishikawa et al. developed a HL self-assessment instrument (Functional, Communicative and Critical Health Literacy scale–FCCHL) which relies on this model and has the aim to measure all three types of HL. It has been recognized as one of the most suitable and comprehensive instruments for measuring health literacy in people with diabetes in healthcare settings [23,24]. Patients with diabetes and limited health literacy often cannot read medication labels accurately, may take medication incorrectly, have less medication adherence, and generally have difficulty understanding instructions for follow-up care [25,26]. These patients also have poorer patient-doctor communications and participate less in decision-making [27].

Altin et al. found out that most HL scales could be deemed multidimensional. The use of multidimensional scales in health-related research far outweighs the number of published studies that apply multidimensional analyses approaches. Multidimensional scale like FCCHL uses subscales to measure different but related aspects in order to capture the complexity of a construct. Multidimensional modeling approaches are appropriate to account for the observed covariance in the data [28,29].

FCCHL has been validated in several populations including French/Dutch/German/Australian/Japanese/Norwegian citizens [21,30–35]. However, no validation of FCCHL exists in Serbian. Validated translations of HL measures are needed, as a growing literature has shown the importance of evaluating HL in patients with type 2 diabetes mellitus (T2DM) [21,36–40]. Permission to use the FCCHL was obtained from the author (Hirono Ishikawa) under e-mail agreement (9 January 2020) and we used the English version of the FCCHL, which includes 14 items.

There is limited knowledge of Functional, Communicative, Critical and total HL in Serbia, and so far, there has been no validated instrument for measuring all these

health literacy levels. Due to a nature of the disease and large distribution of the DMT2 population in Serbia it is of exceptional importance to identify patients' needs and work on improvement of disease control and quality of life of this population. Thus, the aim of this article is to describe the process of translation, cultural adaptation, and validation of the FCCHL instrument into Serbian in order to make it suitable to be used in Serbian healthcare settings.

2. Materials and Methods

2.1. Instrument

The FCCHL is a general perception-based instrument, that is a subjective measure involving respondents to rate their perceived abilities. Across three levels (F-functional, I-communicative (interactive), and C-critical) with answer categories ranging from 1 (never) to 4 (frequent). This self-reported instrument consists of 14 items. FHL1-FHL5, measures reading comprehension. IHL1-IHL5, assess skills in finding, understanding, and applying information and communicating personal views on diabetes. Four items, CHL1-CHL4, critically assess the ability to self-report by assessing the reliability, validity, and applicability of available health-related information. Scores on the functional HL scale were recorded, and mean scores were calculated for each scale ranging from 1 (low health literacy) to 4 (high health literacy) [35]. The current FCCHL does not define cut-off or class values for health literacy.

2.2. Translation and Cultural Adaptation

At the beginning of the preparation for the research, before the validation procedure, it is necessary to adjust the instrument to the language in which the research is conducted, as well as to the population of the participants.

Experts of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) have set guidelines that define the basic principles of translation and adaptation of the instrument: (1) translation preparation, (2) "forward" translation, (3) single "forward" translation, (4) "backward" translation, (5) review of the "backwards" translations, (6) harmonization, (7) cognitive examination, (8) review and (9) final report [41,42].

1. In preparation for translation, people were selected to do the translation (A1, A2, T3 and T4). The methodology is defined, and the author of the instrument was contacted to gain approval for use of the FCCHL instrument.
2. "Forward" translation in our case was the translation of the instrument from the source language (English) into target language (Serbian). This step was performed by two -researches (A1 and A2) whose native language is Serbian, and the other language is the source language of the scale being translated. Both authors were familiar with the concept of the research. They were independent of each other, i.e., all items, answers and instructions were translated separately. When translating, focus was maintained on ensuring that the concept is adequately conveyed and that the wording is clear.
3. Single "forward" translation or the formation of a unified version of the translation involved merging these two researches into one (A12) and this was done by a third person from the team and after discussion between the researchers. This version was with a minimum of disagreement and with the clearest questions in translations.
4. "Backward" translation was done by translating from target language into the source language. It was conducted by two translators (T3 and T4) who are native speakers of the source language and are fluent in the target language. Both back translators were unfamiliar with the content of the instrument.
5. A review of the "backwards" translations considered a comparison of back-translated versions of an instrument with the original to highlight and explore the differences between the original and the aligned translation.
6. The harmonization implies a central place in the whole process and involved comparison of both versions of the "backwards" translations, testing the degree of agreement

of the concepts of all items, making corrections, controlling language errors, and forming a version for the testing phase.

7. The penultimate step in the cultural adaptation process is pre-testing. It is a process in which the final version was introduced into testing on the population for which the instrument was made. Pre-testing was done using the cognitive interviewing technique "probing" with required patients at a health-care institution by a researcher (A1) [29,43]. To gain a better understanding of the cognitive processes the participant used to answer the items thinking aloud, as explicitly instructed. Ten diabetic patients were eligible to fill-in the instrument and discuss it with the interviewer. Interviews were conducted until data saturation was reached; meaning that no more new information of value was obtained. It lasted from 5–6 min.
8. In the review process all reports from previous stages were reviewed in detail, the test results were included in the translation and all disagreements were eliminated. The degree of equality between the target version and the original was assessed, and the result of this step is the creation of the final version of the instrument.
9. The final report considered a review of the final version of the instrument and submission of reports with all collected documents to the author. The authors evaluated and approved the final version of the FCCHL to be used for the validation study. (Figure 1).

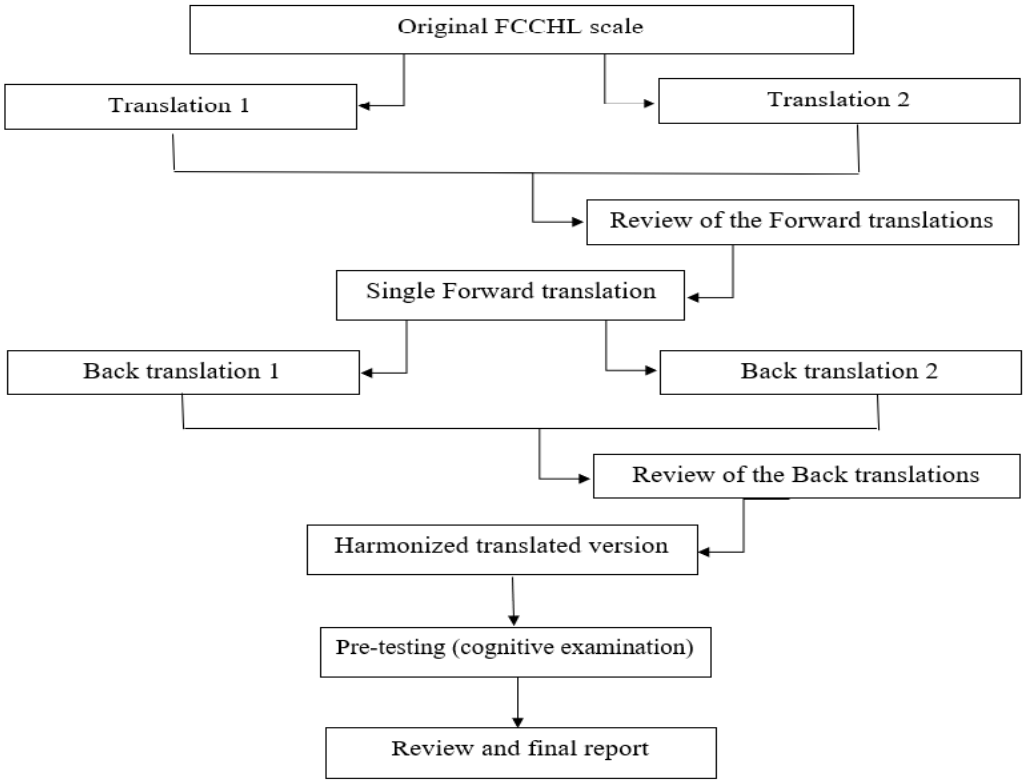

Figure 1. Translation and cross-cultural adaptation steps for FCCHL instrument.

2.3. Quantitative Study

The quantitative study (validation study) was used to evaluate the reliability, structural validity, distributional properties, and convergent validity of the FCCHL-SR14 instrument.

2.4. Sample and Data Collection

The target population of the validation study were patients diagnosed with T2DM at least six months before the start of the study, who knew the Serbian language, aged 18 and older and voluntarily agreed to participate with signed informed consent. The exclusion criteria were participants with medical background (e.g., doctors, study nurses,

pharmacists . . .) and those who provided less than 90% of answers in the instrument. In total, we approached 147 persons, out of which approximately 88% fulfilled the study criteria. We excluded 17 individuals due to not fulfilling 90% of the instrument. The final sample for validation study included 130 individuals. The sample size is often dependent on the length of the instrument, as some authors recommend that the participant-to-item ratio should be at a minimum 5:1 [44]. Larger sample sizes could provide more meaningful factor loadings and factors and yield more generalizable results, so we opted for a participant-to-item ratio of 10:1.

This study was carried out at one healthcare center and one community pharmacy randomly chosen from two different municipalities in the Belgrade region. Patients from all parts of those municipalities were represented to reflect the geographical distribution in the target population. Data for this cross-sectional study were collected between January 2021 and June 2021 and between March and April 2022, using a self-administered paper-and-pencil instrument. Before the survey, we recruited five research assistants to help us with collecting data. To ensure that they were familiar with the purpose, process, and procedure of applying the instrument, we systematically trained three pharmacy graduates and two doctors as research assistants. Throughout data collection, the researchers and assistants explained the purpose and significance of the study to the participants and obtained written informed consent. Participants did not receive any payment for filling out the instrument. All data was anonymous and, as such, entered into the database.

Demographic variables were collected, such as gender, age, education level, self-reported general health condition, life habits and questions related to diabetes.

2.5. Data Analysis

We used mean value and standard deviation (SD) for normally distributed data, median and 25. and 75. percentile values for skewed data and absolute and relative frequencies to characterize the study sample. Also, we calculated FCCHL total scores and domain scores. Normality of distribution was tested by the Kolmogorov Smirnov test. To describe the FCCHL we also analyzed minimal and maximal values for each item. Distributional properties of the instrument (skewness and kurtosis) were further inspected to examine the normality of the scores on each subscale and to identify floor and ceiling effects. Floor or ceiling effects were considered to be present if >15% of the patients scored the worst or the best possible score [45].

The comparative fit index (CFI), the standardized root mean square residual (SRMR), and the root mean square error of approximation (RMSEA) were used to examine the model fit. Normed $\chi^2 < 3$, CFI values ≥ 0.95 and SRMR and RMSEA values < 0.08 and ≤ 0.06, respectively, were considered indicative of good model fit [46]. However, RMSEA values of 0.08 could indicate an acceptable fit [47,48]. Factor loadings over 0.71 were considered excellent, 0.63 very good, and 0.55 good [45]. To improve the model with inadequate fit, e.g., when CFI, SRMR, and RMSEA were unsatisfactory, we examined the modification index (MI) and allowed to correlate measurement errors, or we removed items with the lowest factor loadings. We compared the first and final model by computing a χ^2 difference test to assess incremental fit. According to this test and recalculated coefficients, we decided whether a new models fit significantly better than the given model.

After confirming the instrument's validity, reliability was assessed by internal consistency and test-retest methods. In the internal consistency method, consistency of the results of the tool items was investigated, and then the Cronbach's alpha coefficient was calculated for the items in each domain and the whole instrument. Test-retest reliability or consistency in answering items was examined by asking 29 patients with T2DM who participated in the validation process to refill the same instrument after four weeks. Interclass correlation coefficient (ICC) was calculated for the items in each domain and the whole instrument. Overall, p values less than 0.05 were considered significant [49,50].

All analyses were performed using IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY, USA: IBM Corp except for CFA. It was conducted by Jamovi Statistical Software (Idaho State University).

2.6. Ethical Considerations

This study was approved by the Ethics committee of the Healthcare Centre "Zvezdara" (ref. no. 4411-3) and by the Ethics committee of the Pharmacy "Filly farm". Participation was voluntary, and the instrument was completed anonymously.

3. Results

3.1. Report of Translation

During the translation process, minor issues were identified by the third person who was involved in the review of "forward" translations and a consensus version was agreed between authors and the reviewer of the translation before re-translation to the source language. During the reconciliation process, the researches have accepted the use of Serbian translation for "diabetes (sugar disease)" covering the word "diabetes" in English, with the aim to explain the medical term to the participants.

3.2. Pre-Testing

The mean age of interviewed participants in the first pre-test was 62.7 years (SD = 12.4), ranging from 34 to 79 years of age. Of the 10 respondents, just over half were men (60%). 50% had completed education at a higher school, university, or university PhD level, and about the same proportion had completed primary and secondary school. Participants primarily lived in urban areas (60%) and on average it took them 3 min to complete the instrument.

No item was considered irrelevant by the participants. Examples of the input of the respondents' comments during the development of the FCCHL-SR14 instrument are introduced in Table 1 (cultural adaptation) and Table 2 (linguistic adaptation).

Table 1. Cultural adaptation of the items from the FCCHL-SR14 instrument included in the discussion after pre-testing.

	Initial Variant of the Item	Suggestions after Pre-Testing	Changes
FHL1	Found that the print is too small to read	It was unclear for respondents whether it is applicable in the case of wearing glasses Suggestion: to add 'even with glasses'	Found that the print is too small to read even though you wear glasses
FHL4	Found the content too difficult	It was unclear what it meant to be too difficult Suggestion: to add 'to understand'	Found the content too difficult to understand
FHL5	Needed someone to help you read them		Needed help from another person in order to understand
IHL1	Collected information from different sources	Respondents were not sure what the different sources represent Suggestion: to add examples	Collected information from different sources (for example pharmacist, rheumatologist, general practitioner...)
IHL2	Extracted the information you wanted	It was unclear for participants what this item presents Suggestion: to clarify with adding 'only'	Extracted (only) information you wanted
IHL4	Communicated your thoughts about your health to someone	Respondents were confused by the term someone Suggestion: To clarify the term with examples	Communicated your thoughts about your health to someone (for example you children at home, your doctor, colleagues...)

Table 2. Linguistic adaptation of the items from the FCCHL-SR14 instrument included in the discussion after pre-testing.

	Initial Variant of the Item	Suggestions after Pre-Testing	Changes
FHL2	Found characters and words that you did not know	Rephrased from "did not know" to "unfamiliar" for better understanding	Found unfamiliar characters and words
CHL4	Collected information to make decisions about your health	Changed to be in the spirit of the language	Collected information to make health-related decisions

The form of the instrument was adjusted based on the advice of a few participants, who did not manage at first that there were 14 separate items for the three categories with four answers offered (Never, Rarely, Sometimes and Often), the font was increased, and it was decided to be in the form of landscape so that elderly can also read with ease.

3.3. Subjects

In Table 3, sample characteristics of the validation study are shown. Mean age was 58.2 years with 63.8% of the sample being female. On average, patients have had T2DM for 11 years.

Table 3. Characteristic of 130 participants in the validation study.

	n (%)
Marital status	
Unmarried	15 (11.5%)
Married/Common-law	85 (65.4%)
Divorced	17 (13.1%)
Widow	13 (10%)
Children	
Yes	102 (78.5)
No	28 (21.5)
Number of children	
One child	30 (24.6)
Two children	57 (46.7)
Three or more children	14 (11.4)
Education	
4 classes or no school	1 (0.8%)
Primary school	5 (3.8%)
High school	44 (33.8%)
Higher school (VI grade)	29 (22.3%)
University	48 (36.9%)
Master's degree/Specialization/PhD grade	3 (2.3%)
Employment	
Incapable	2 (1.5%)
Unemployed	10 (7.7%)
Student	1 (0.8%)
Employed	77 (59.2%)
Pensioner	39 (30.0%)
Monthly income per family member	
≤27,000 RSD *	16 (12.3%)
27,000–40,000 RSD	22 (16.9%)
≥40,000–60,000 RSD	86 (66.2%)
≥60,000 RSD	6 (4.6%)

Table 3. *Cont.*

	n (%)
Chronic diseases	
T2DM	43 (33%)
T2DM and additional chronic diseases	87 (67%)
Therapy for T2DM	
Diet	1 (0.8 %)
Tablets	83 (63.8 %)
Tablets and Insulin	36 (27.7 %)
Insulin	10 (7.7 %)
Frequency of drug administration for T2DM	
Once a day	8 (6.2%)
Twice a day	69 (53.1%)
Three times a day	37 (28.5%)
Four times a day	15 (11.5%)
I don't use drugs for T2DM	1 (0.8%)
Active exercise	
Never	27 (20.8%)
Less than once a week	46 (35.4%)
1–2 times a week	37 (28.5%)
3 and more times a week	20 (15.4%)
Smoker	
≤1 box a day	35 (26.9%)
>1 box a day	18 (13.8%)
Not smoker	68 (52.3%)
Ex-smoker	9 (6.9%)
Alcohol	
Never	74 (56.9%)
Once a month	35 (26.9%)
2 or more times a month	21 (16.2%)
Source of health information	
Doctors	67 (51.5 %)
Pharmacists	9 (6.9 %)
Parents	1 (0.8 %)
Internet	18 (13.8 %)
Friends	1 (0.8 %)
Books/Magazines/TV	3 (2.3 %)
Doctors and Pharmacists	27 (20.8 %)
Doctors and Internet	1 (0.8 %)
Doctors, Pharmacists, and Internet	3 (2.3 %)
Interest in health	
Not interested	3 (2.3%)
Little	22 (16.9%)
Medium	66 (50.8%)
Much	21 (16.2%)
Very interested	18 (13.8%)
Self-estimation of health status	
Very bad	6 (4.6 %)
Bad	31 (23.8 %)
Good	77 (59.2 %)
Very good	16 (12.3 %)

Note. * 1 RSD = 0.0085 EUR.

3.4. Distributional Properties

Items in IHL and CHL domains showed no skewness or kurtosis in the distribution of scores. One item in FHL domain (small print) kurtosis was negative and indicated the small outliers in a distribution (Table 4). There was no floor (14.6% FHL; 12.3% CHL; 10.8% IHL, respectively) or ceiling effects in each HL score (4.6% FHL; 8.5%CHL; 9.2%IHL, respectively).

Table 4. Distribution of scores.

FHL	(1) Small Print	(2) Unfamiliar Characters and Words	(3) Difficult Content	(4) More Time Needed	(5) Needed Help
Mean	2.05	2.17	2.32	2.19	2.51
Median	2.00	2.00	2.00	2.00	3.00
Standard deviation	0.951	0.916	0.856	0.872	0.950
Skewness	0.331	0.147	0.077	0.183	−0.022
Kurtosis	−1.05	−1.00	−0.653	−0.756	−0.899
Standardized factor loadings	0.543	0.722	0.641	0.733	0.689
IHL	(1) Information sources	(2) Wanted information	(3) Understanding the information gathered	(4) Sharing thoughts with someone	(5) Application of information
Mean	2.48	2.52	2.78	2.79	2.60
Median	2.00	2.50	3.00	3.00	3.00
Standard deviation	0.865	0.799	0.853	0.938	0.886
Skewness	0.048	0.062	−0.177	−0.202	−0.003
Kurtosis	−0.628	−0.436	−0.660	−0.929	−0.734
Standardized factor loadings	0.599	0.490	0.549	0.696	0.756
CHL	(1) Considered the applicability of the information	(2) Credibility of information	(3) Checking the accuracy of information	(4) Collecting information	
Mean	2.72	2.47	2.48	2.65	
Median	3.00	2.00	3.00	3.00	
Standard deviation	0.872	0.873	0.837	0.929	
Skewness	−0.283	−0.011	−0.071	−0.019	
Kurtosis	−0.543	−0.663	−0.550	−0.911	
Standardized factor loadings	0.772	0.675	0.604	0.752	

3.5. Structural Validity and Reliability and Suggested Modifications to the FCCHL-SR14

Structural validity was examined by CFA. When we analyzed all 14 items (FCCHL-SR14), loading factors were between 0.49 and 0.77 (Table 4), but without adequate model fit (Table 5). Examining MI of the unique-error terms, we found that two correlated-error terms had MIs greater than 10-one for FHL questions (between 1st item (FHL1) "Found that the print is too small to read even though you wear glasses" and 2nd item (FHL2) "Found unfamiliar characters and words" (MI was 19.2) and one for IHL questions (between the 1st item (IHL1) "Extracted only information you wanted" and the 2nd item (IHL2) "Collected information from different sources" (MI was 14.8). We rerun the FCCHL-SR14 model, first freeing the largest correlated error and, after that, the second. As seen in Table 5, the modified FCCHL-SR14 model fit the data significantly better when it included the one correlated-error terms with the largest MI (MI or $\Delta\chi^2 = 19.2$; $p < 0.001$). Although the model's fit coefficients were improved, its CFI was still below 0.90. We thus freed the other correlated error with MI = 14.8 and reestimated the model. The model including two correlated-error terms significantly improved the model's fit ($\Delta\chi^2 = 14.8$; $p < 0.001$) but still without appropriate fit coefficients. In the next step, we examined the factor loadings for each of the two pairs of questions that shared measurement error to remove the question with the lower factor loading. Questions with shared measurement error in FHL domain were FHL1 and FHL2 with factor loadings of 0.439 and 0.643, respectively; in IHL domain were IHL1 and IHL2 with factor loadings of 0.556 and 0.431, respectively.

Table 5. Models fit coefficients.

Model	χ^2	df	*p*	CFI	SRMR	RMSEA (90%CI)
FCCHL-SR14	192	74	<0.001	0.819	0.0779	0.111 0.092–0.130
Modified FCCHL-SR14 with one correlated error	173	73	<0.001	0.846	0.0753	0.103 0.084–0.123
Modified FCCHL-SR14 with two correlated error	158	72	<0.001	0.867	0.0731	0.0961 0.0761–0.117
FCCHL-SR12	96	51	<0.001	0.916	0.0676	0.0831 (0.057–0.108)
Δ FCCHL-SR14-FCCHL-SR12	96	23	<0.001			

After removing two items with the lowest loadings, FHL1 (Found that the print is too small to read even though you wear glasses) and IHL2 (Extracted (only) information you wanted) in the modified FCCHL-SR12 the fit indexes indicated a reasonable normed χ^2 (SB scaled χ^2/df = 1.88). As seen in Table 5, FCCHL-SR12 was not worse than FCCHL-SR14 (χ^2 difference *p* value was < 0.001). CFI, SRMR, and RMSEA for FCCHL-SR12 indicated a good model fit and the second model was retained. Standardized factor loadings ranged between 0.54 and 0.79 for the correlated 3-factor model of the HL scales in the total sample (n = 130). Rectangles represent the observed variables (items) and ellipses represent the hypothesized latent constructs (factors). Values on the single-headed arrows leading from the factors to the items are standardized factor loadings. Values to the left of the items represent error variances. Values on the curved double-headed arrows are correlations between factor terms. (Figure 2).

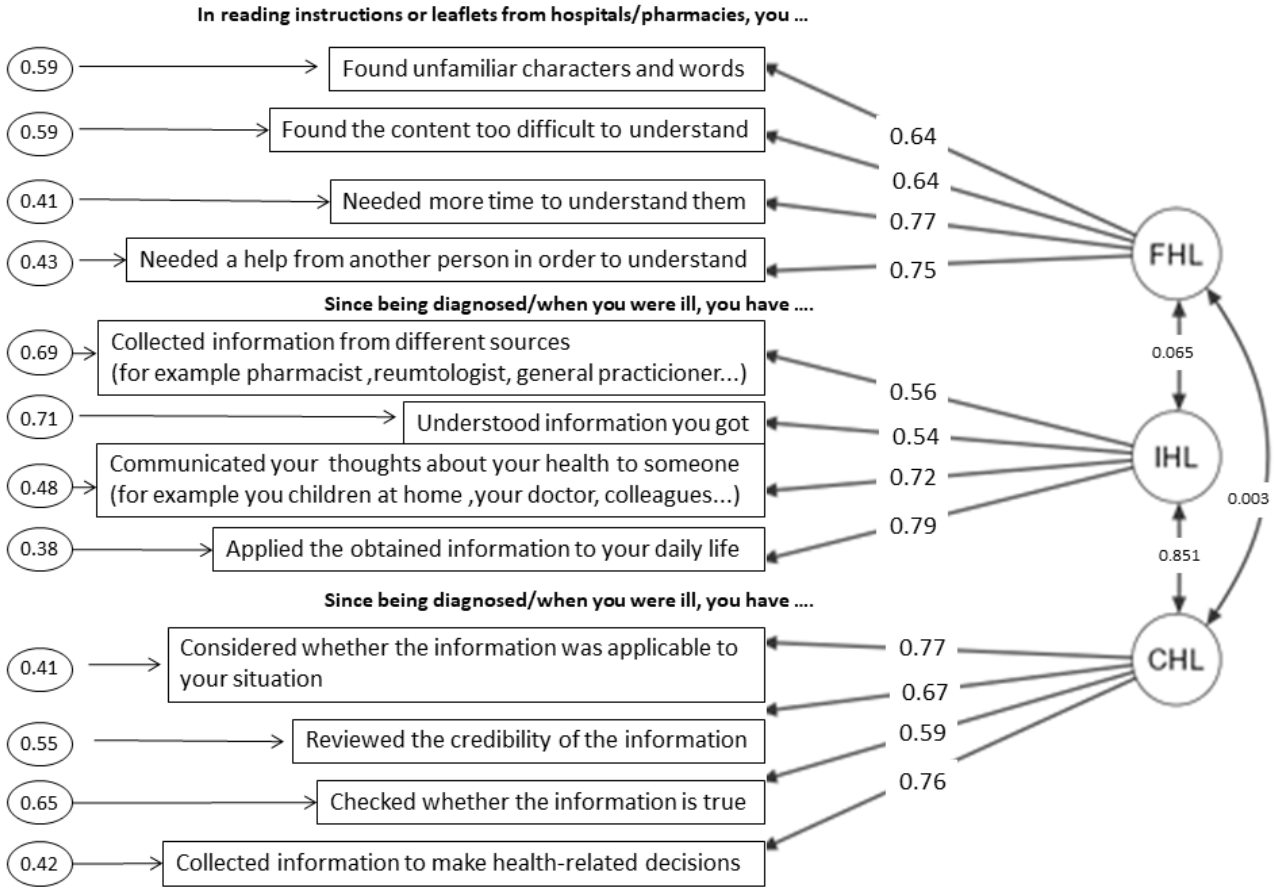

Figure 2. Summary of Structural Validity.

The highest subscale correlation was observed between the IHL and CHL subscales (r = 0.851). Independent of the modeling approach, the lowest factor loadings were observed for the items FHL1 and IHL2.

The FCCHL-SR12 instrument was assessed by internal consistency and test-retest methods. To determine internal consistency, Cronbach's alpha coefficient in a sample of 130 patients was 0.767 for the whole FCCHL-SR12 with 95% confidence intervals from 0.703 to 0.822. However, this value varied from 0.792, 0.748, and 0.796 for functional, communicative, and critical constructs, respectively.

To determine the instrument's consistency in the repeatability dimension, in a group of 29 patients with four weeks' interval, the ICC for the whole instrument was calculated to be 0.981 with 95% confidence intervals (0.960–0.991). This value varied from 0.980 to 0.960 and 0.972 in functional, communicative, and critical domains, respectively

4. Discussion

4.1. Cultural and Linguistic Adaptation of the FCCHL-SR Instrument

Like in other studies investigating the FCCHL [29–35] our results indicate that, after translating and adapting the FCCHL instrument to Serbian, the FCCHL-SR12 is a valid instrument, ready to be used in Serbia, and opening possibilities to study HL in Serbia and compare the results internationally.

We found that inclusion of lay people helped a lot in designing and simplification of the instrument, for being consistent with the broad and inclusive definition of HL. The pre-testing was an important step in the translation process, which eventually led to the Serbian version of FCCHL. Even though the specialist review turned out to be essential regarding accepted language within the health and social setting, the pre-testing gave vital information about the understanding of actual people who might answer the instrument. Including the target audience when translating instruments to another language and their influence on the adaptation is crucial for creation of a valid and reliable instrument to be used in clinical practice settings.

Patients with T2DM perceived some difficulties in filling out the items. Some items left room for interpretation, and additional clarification/examples were provided to give patients a better idea of the concept.

4.2. The 12-Item FCCHL-SR

Similar to the study in Norway [34], FCCHL-SR12 has several benefits over the FCCHL-SR14 version. The FCCHL-SR12 has a better normed χ^2, CFI, SRMR and RMSA, and the remaining FHL and IHL items had a better fit to the model.

Respondents who stated in FHL1 that they "found that the print was too small to read" could indicate their opinions about the font size, font type, or their sight variables-which might be independent of HL. After pre-testing, the item was rephrased with the addition "even though you wear glasses" and in this way, the item was better clarified. In addition, in IHL2-"extracted information you wanted" confused participants since it is too general, and they suggested adding "only" in between. Considering the lowest factor loadings of these two items and unclarities among participants, they were removed after discussion.

4.3. Methodological Considerations

In accordance with previous studies [29,30,33], exploratory analysis revealed a 3-factor model confirming the overall structure of the scale, with satisfactory internal consistency of each FCCHL dimension.

Regarding the distributional properties of the instrument, there were no floor or ceiling effects in each HL score, the same as in some other studies [31,33,51], which shows that we cannot expect a distribution problem with lower ability to differentiate people with very low and very high health literacy levels. We have the same results for distribution of scores with previous findings on this instrument [29].

The instrument showed a good internal consistency (Cronbach's alpha coefficient = 0.84, 0.77 and 0.65 respectively) in the study from Ishikawa [35], and its three-level structure looked promising for the measurement of the full spectrum of HL. Our findings differ slightly from previous findings in the Netherlands [29] and Australia [32], which found that internal consistency of the communicative dimension was less satisfactory ($\alpha = 0.63$ in both studies). However, due to this difference, the instrument should be further investigated in larger samples.

The subscale correlation was observed between the IHL and CHL subscales, which suggests that the measurement of IHL can be substituted for the measurement of CHL. As FHL is defined as basic skills, while communicative HL and critical HL are defined as advanced skills [29], use of FCCHL-SR12 instrument may contribute to promoting a better understanding of advanced skills beyond reading comprehension and numeracy.

Responding to self-administered measures could be quite challenging for people with limited FHL since it requires reading and reading comprehension abilities. However, the participants reported that the items were clearly stated, while they were being interviewed.

This study provides evidence for the reliability and validity of the FCCHL-SR12.

4.4. Advantages of FCCHL Scale

While other scales focus on functional health literacy, this scale aims to measure the broader concept of health literacy, including the ability to retrieve, understand, and use health-related information.

Health literacy has been presented as a measurable and important concept in considering education for patients with chronic diseases such as diabetes. In addition to the previous instruments that focus exclusively on functional health literacy, this scale covers all three levels of health literacy, each of which can have different effects on patient outcomes. Also, the scale is easy to apply in clinical conditions.

Exploring the functional, communicative, and critical levels of patients' health literacy can help physicians and other health care workers to better understand their patients' potential barriers to disease self-management and health-promoting behaviors [36].

4.5. Limitations

HL was assessed with a self-report instrument which could lead to social desirability and an overestimation of the HL level, as individuals are often ashamed of their inability to read. The study can be performed in a larger population.

5. Conclusions

The FCCHL scale was selected for translation, adaptation, and validation because it is short, easy to administer, and it is the only instrument for health literacy which measures individually functional, communicative, and critical health literacy as well as the total health literacy. The findings indicated that the Serbian version of FCCHL (FCCHL-SR12) is comparable to the original model and according to the model fit, a three-dimensional approach (where the correlations between the subscales are taken into account) is recommended when using the FCCHL to describe HL in people with T2DM. This opens possibilities to study HL at health-care settings in Serbia and internationally compare the results. The specialist review and pre-testing provided essential additional information to the translation/back-translation procedure. Adaptations that were made helped to bring the instrument closer to the target group. FCCHL-SR12 demonstrated adequate reliability and validity as an internal measure for Serbian patients with T2DM. This validated model might be helpful in the countries where there is a lack of validated tools for measuring HL levels. Future research on a larger population in Serbia is necessary in order to draw conclusions about the levels of HL and their relationship with other determinants in this country.

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Institutional Review Board Statement: The study adhered to the ethical standards in line with the International Ethical Guidances for Health-related Research Involving Humans (the Council for Intrenational Organizations of Medical Sciences, CIOMS, 2016).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Conflicts of Interest: The authors declare no conflict of interest.

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UNIVERZITET U BEOGRADU
FARMACEUTSKI FAKULTET
03 br. 4/116
29.09.2020 godine

Na osnovu Statuta Univerziteta u Beogradu, prodekan Fakulteta je dana 30.09.2020 godine, donela

O D L U K U

ODOBRAVA se Lević Marija, studentu Farmaceutskog fakulteta, indeks br. 12/14, produžetak roka za završetak studija za školsku 2020/21.

O b r a z l o ž e n j e

Lević Marija, student na studijskom programu DAS - Soc. farm. i ist., podneo je zahtev 03 br. 4/116 od 29.9.20. godine prodekanu Fakulteta da mu se odobri produžetak roka za završetak studija.

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Odluku dostaviti: Imenovanoj-om, dekanu i Odseku za nastavu i studentska pitanja.

PRODEKAN ZA POSLEDIPLOMSKU NASTAVU
I KONTINUIRANU EDUKACIJU

Prof. dr Sandra Vezmar Kovačević

20.10.2020. Marija Lević

UNIVERZITET U BEOGRADU
FARMACEUTSKI FAKULTET
03 br. 4/182
30.09.2021 godine

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ODLUKU

ODOBRAVA se Mapiju Ilebuć, studentu Farmaceutskog fakulteta, indeks br. 12/14, produžetak roka za završetak studija za školsku 2021/22.

Obrazloženje

Mapija Ilebuć, student na studijskom programu DAS-SOC.FAR.I ISTRŽ FAR.PR podneo je zahtev 03 br. 4/182 od 30.09.2021. godine prodekanu Fakulteta da mu se odobri produžetak roka za završetak studija.

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Odluku dostaviti: Imenovanoj-om, dekanu i Odseku za nastavu i studentska pitanja.

PRODEKAN ZA POSLEDIPLOMSKU NASTAVU
I KONTINUIRANU EDUKACIJU

Prof. dr Sandra Vezmar Kovačević

Mapija Ilebuć
12.10.2021

UNIVERZITET U BEOGRADU
FARMACEUTSKI FAKULTET
03 br. 3/24
02.06.2023. godine

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REŠENJE

ODOBRAVA se Lević Marији, studentu Farmaceutskog fakulteta, indeks br. 12/2014, mirovanje prava i obaveza studenta za školsku 2022/23. godinu.

Obrazloženje

Lević Marija, student na studijskom programu DAS: Socijalna farmacija, podneo je zahtev 03 br. 3/24 od 02.06.2023. godine prodekanu za nastavu Fakulteta da mu se odobri mirovanje prava i obaveza za školsku 2022/23. godinu. Uz molbu je priložio odgovarajuću dokumentaciju.

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Rešenje dostaviti: Imenovanom, dekanu, prodekanu za nastavu, sekretaru, Odseku za nastavu i studentska pitanja i arhivi.

PRODEKAN ZA POSLEDIPLOMSKU NASTAVU
I KONTINUIRANU EDUKACIJU

Prof. dr Sandra Vezmar Kovačević

UNIVERZITET U BEOGRADU
FARMACEUTSKI FAKULTET
03 br. 3/63
07. 09. 2023. godine

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REŠENJE

ODOBRAVA se Lević Mariji, studentu Farmaceutskog fakulteta, indeks br. 12/14, mirovanje prava i obaveza studenta za školsku 2023/24. godinu.
od 01.10.2023. do 01.04.2024.

Obrazloženje

Lević Marija, student na studijskom programu DAS: SFIF7, podneo je zahtev 03 br. 3/63 od 07. 09. 2023 godine prodekanu za nastavu Fakulteta da mu se odobri mirovanje prava i obaveza za školsku 2023/24. godinu. Uz molbu je priložio odgovarajuću dokumentaciju.

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Rešenje dostaviti: Imenovanom, dekanu, prodekanu za nastavu, sekretaru, Odseku za nastavu i studentska pitanja i arhivi.

PRODEKAN ZA POSLEDIPLOMSKU NASTAVU
I KONTINUIRANU EDUKACIJU

Prof. dr Sandra Vezmar Kovačević

28.09.23.

УНИВЕРЗИТЕТ У БЕОГРАДУ
ФАРМАЦЕУТСКИ ФАКУЛТЕТ
Посл.број: 5/39
Дана **01.04.2024**. године

На основу Статута Универзитета у Београду, продекан Факултета је дана 01.04.2024. године, донела

О Д Л У К У

ОДОБРАВА се ЛЕВИЋ МАРИЈИ, студенту Фармацеутског факултета, индекс бр. **12/2014,** продужетак рока за завршетак студија за период од годину дана од 01.04.2024.г. до 01.04.2025.године.

О б р а з л о ж е њ е

ЛЕВИЋ МАРИЈА, студент на студијском програму **ДАС – Социјална фармација и истраживање фармацеутске праксе,** поднела је захтев број 5/39 од 01.04.2024. године продекану Факултета да јој се одобри продужетак рока за завршетак студија за период од годину дана од 01.04.2024.г. до 01.04.2025.године.

Продекан Факултета је разматрала захтев 01.04.2024.године и оценила да је захтев основан, те је донето решење као у диспозитиву.

ПРАВНА ПОУКА: Против ове одлуке именовани има право приговора декану Факултета у року од 8 (осам) дана од дана пријема истог.

Одлуку доставити: Именованој-ом, декану и Одсеку за наставу и студентска питања.

ПРОДЕКАН ЗА ПОСЛЕДИПЛОМСКУ
НАСТАВУ
И КОНТИНУИРАНУ ЕДУКАЦИЈУ

Проф. др Сандра Везмар Ковачевић